EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Support for Lead-Based Paint

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate WA for 2-01, Contractor shall provide work plan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	06/13/2016 To 06/12/2019		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Darlene Leonard (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0516
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

Battelle
Contract Number: EP-W-16-017

Work Assignment Number: 2-01
Change Number: 0

Title: Support for the Lead-Based Paint Program and Other National Program Chemicals

I. Purpose and Background

To provide technical support of the implementation of the Renovation, Repair and Painting Program (RRP) as well as all other aspects of the Lead-Based Paint Program. This is a continuation of work to extend the performance period that began under the previous work assignment, Work Assignment 1-01 of contract EP-W-16-017. No work shall be duplicated and no cost shall be added.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. These actions include technical studies to support rule making, outreach to the regulated community, outreach to the public and support of the regulatory functions.

Additionally, technical support is needed for other work in the National Program Chemicals Division (NPCD). NPCD is responsible existing chemicals that are ready for hazard management. Currently those chemicals include lead, mercury, formaldehyde, asbestos, dioxin and polychlorinated biphenyls (PCBs).

II. Scope of Work:

Task 1 Storage of Records

The Contractor shall arrange for storage facilities for RRP paper records. These are active records and must be available in the Washington, D.C. metropolitan area. The records must be stored in a secure area and be available for EPA personnel within 24 hours. When directed by the Contracting Officer Representative (COR), the Contractor shall arrange for pickup of additional records from within another location in the Washington, D.C. area. The Contractor shall maintain the existing filing methodology and file any new records accordingly.

Task 2 Cleaning Verification Cards

When directed by the COR, the Contractor shall provide Cleaning Verification Cards that meet the quality control standards previously developed. The cards shall be shipped to the National Lead Information Center in Rochester, NY. It is anticipated that the cards will be produced in batches of 150,000. Assume one batch will be required.

Task 3 Support of the Outreach Efforts at Trade Shows

When directed by the COR, the Contractor shall purchase exhibit space at trade shows and shall staff the EPA-provided booth. These services include shipping the EPA booth to the show and returning it to a location designated by the COR. Also included in this task is paying for incidental fees such as drapes, delivery charges, etc.

Task 4 Technical Studies

When directed by the COR, the Contractor shall produce studies on Lead-Based Paint issues. These studies are anticipated to be of short duration, typically less than 30 days. The exact nature of the study and due date will be contained in the technical direction. Anticipated topics are work practices on Public and Commercial Buildings and other rules in development. Also providing additional analyses on the Dust Study is anticipated.

Task 5 Revisions to Major Documents

When directed by the COR, the Contractor shall provide draft documents of revisions to major documents such as "Protect Your Family" (PYF) and training manuals. It is anticipated that there will be several drafts of both the revised text and graphics. PYF is a joint publication of HUD and EPA and will need to be cleared by both agencies. The Contractor shall produce both and English and Spanish versions of the document. It may be necessary for the Contractor to convene one or more focus groups in both English and Spanish to determine the readability and understandability of the document. There may be other national program chemical documents to be revised, including special tasks for mercury and PCBs.

Task 6 Lead Outreach Support

When directed by the COR, the Contractor shall provide support to a major outreach effort on outreach to the regulated community on the Renovation, Repair and Painting Rule and/or other regulations or topics related to lead. The Contractor shall provide assistance with identifying target audiences. This includes the purchase of mailing lists and associated services and purchase of advertising.

Task 7 National Program Chemicals Support

When directed by the COR, the Contractor shall provide support to other national program chemicals including but not limited to mercury, formaldehyde, dioxin furans, asbestos and PCBs. The Contractor shall provide technical support for regulatory and non-regulatory activities involving risk reduction and hazard management of national program chemicals. Technical support includes but is not limited to technical studies and investigation supporting rule making, outreach to the regulated community, outreach to the public and support of regulatory and non-regulatory functions.

III. Deliverables:

Tasks 1 to 3: A letter report providing statistics on the activity for the contract period shall be provided. This can be part of the monthly report.

Task 4. A draft and final report as detailed in the technical direction.

Task 5. Electronic and/or CDs of the professional print files of the documents ready for printing and/or posting onto the EPA webpage.

Task 6. A letter report detailing the activities performed.

Task 7. A draft and final report as detailed in the technical direction.

A work plan is not required. A financial plan is required.

A QA/QC plan is required for Tasks 4 and 7. A QA/QC plan is not required for Tasks 1, 2, 3, 5 and 6.

CBI does not apply.

This work assignment relates to Tasks II, III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on June 13, 2018 and extend through June 12, 2019.

V. Level of Effort

The approximate LOE is 750 professional hours.

VI. EPA Contacts:

Contracting Officer Representative:
Darlene Leonard
US EPA National Program Chemicals Division
Program Assessment and Outreach Branch (7404T)
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Deputy Contracting Officer Representative:
Julie Shannon

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-02

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Lead Outreach

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW: Lead Outreach

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate WA for 2-02; Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Darlene Leonard (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0516
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
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Battelle
Contract Number: EP-W-16-017

Work Assignment Number: 2-02
Change Number: 0

Title: RRP Lead Outreach

I. Purpose and Background

This project is a continuation of WA 1-02 under Contract EP-W-16-017. This Work Assignment continues and expands upon the work initiated in WA 1-02 under Contract EP-W-16-017 and provides technical support for the implementation of the Renovation, Repair and Painting Program as well as all other aspects of the Lead-Based Paint Program. No work shall be repeated that was previously completed in WA 1-02.

Title IV of the Residential Lead-Based Paint Poisoning Prevention Act requires EPA to undertake various actions to reduce the incidence of lead poisoning. Specifically Section 405 (a) says " The Administrator, in cooperation with other appropriate Federal departments and agencies, shall conduct a comprehensive program to promote safe, effective, and affordable monitoring, detection and abatement of lead-based paint and other lead exposure hazards" Section 405 (d) says "the Administrator in conjunction with the Secretary of Health and Human Services…and in conjunction with the Secretary of Housing and Urban development, shall sponsor public education and outreach activities to increase public awareness…"

Throughout the year, EPA provides lead awareness and educational outreach to various audiences. In addition, EPA partners with the Centers for Disease Control and Prevention (CDC) and the Department of Housing and Urban Development (HUD) to collaborate on a theme and develop posters and flyers and other education and awareness tools and events specifically designed to observe National Lead Poisoning Prevention Week (NLPPW). EPA also promotes the International Lead Poisoning Prevention Week, a lead awareness effort on an international scale.

II. Scope of Work

Task 5 General Lead Outreach

The Contractor shall:

- Provide technical support for general lead outreach, including finalizing EPA pamphlets, poster, banners, flyers for web posting or printing, developing outreach presentations, support for developing, shipping and staffing conference exhibit booths and meetings, translation of existing EPA documents into additional languages, and outreach support involving Historically Black Colleges and Universities (HBCUs) as directed by the EPA Contracting Officer Representative.

III. Deliverables:

- Summary of Work
  The Contractor shall provide a letter report providing statistics on the activity for the contract period.

- Graphic Files and Support
  The Contractor shall provide graphic print files for documents (pamphlets, posters, banners, flyers, social media postings, and other tools) and support for other outreach events and activities, as directed by the EPA Contracting Officer Representative.

A work plan is required.
A Quality Assurance Project Plan is not required since no data collection applies.
CBI does not apply.

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:

This work assignment will start on June 13, 2018 through June 12, 2019.

V. Level of Effort:

The level of effort is estimated to be 15 professional hours.

VI. EPA Contacts:

Contracting Officer Representative:
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Deputy Contracting Officer Representative:
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021	Tech Support for PCB Permit
	Base Option Period Number 2	

Contractor: Battelle Memorial Institute

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate WA for 2-03; Contract shall provide a work plan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2021		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Jennifer McLeod (Signature) (Date)	Branch/Mail Code: Phone Number: 703-308-8459 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

Statement of Work

Battelle
Contract Number: EP-W-16-017
Work Assignment: 2-03
Amendment Number: 0
Title: Technical Support for PCB Permits and Document Development

Background

This project is a follow-on to WA 2-03. This WA 2-03 will address 8 on-going tasks in support of the PCB program, and will be funded incrementally as funding becomes available.

Scope of Work

This WA will cover the following 8 PCB tasks, with those tasks marked as being initially funded in FY18:

Task 1 will involve task management, including work plan development. **This task will be funded in FY18.**

Task 2 will involve sample collection and analysis during on-site the PCB disposal or decontamination demonstrations.

Task 3 will involve PCB disposal and decontamination demonstration requiring review of sampling protocols, including stack emissions.

Task 4 will involve providing sampling kits and performance evaluation (PE) samples for PCB demonstrations.

Task 5 will involve updating the PCB Guidance that will help persons apply for PCB approvals for alternative technologies under 40 CFR §761. **This task will be funded in FY18.**

Task 6 will involve compiling the annual PCB reports into spreadsheets and graphs.

Task 7 will involve PCB notifications and approvals database entry into RCRAInfo. **This task will be funded in FY18.**

Task 8 will involve assisting the agency with making potential regulatory changes to the PCB regulations.

Tasks

Task 1. Task Management

The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

When Tasks 2 and 4 are funded, this WA will require a Quality Assurance Project Plan (QAPP) and will require the use of TSCA CBI.
Quality Assurance Project Plans (QAPP) are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. In addition to abiding by its own Quality Management Plan that has been approved by EPA, all tasks that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

All major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The QAPP does not have to be submitted at the same time as the Technical and Financial Work Plan unless the environmental data activities covered under the QAPP must begin immediately. In many cases, planning for how to perform the work is needed before the QAPP can be prepared and submitted to EPA for approval. For example, under Task 2, when funded, the QAPP will be submitted when appropriate; however, no work involving the generation, collection, analysis and use of environmental data can begin until an EPA approved QAPP is in place.

NOTE: The tasks below represent all of the possible items that may be required by EPA to support the PCB cleanup and disposal program. Written technical direction will be provided by the COR which will specify the items and quantities needed for each permit.

Task 2. Sample Collection and Analysis

A. EPA will observe on-site the PCB Disposal or Decontamination Demonstrations and will collect samples and transfer the samples to the Contractor. The Contractor shall analyze the samples appropriately, as outlined below.

(1) For analysis of polychlorinated biphenyls (PCBs), the Contractor shall analyze samples for classes of PCB compounds called Aroclor. These compounds include but are not limited to the following:

Aroclor 1242	Aroclor 1260	Aroclor 1016
Aroclor 1254	Aroclor 1264	

(2) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify the 209 congeners of polychlorinated biphenyls.

(3) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify PCBs, separating and quantitating the identified PCBs in homologs from mono- to deca-chlorinated biphenyls. The analytical standard to be used shall be the Dry Color Manufacturer Association (DCMA) standard or equivalent.

(4) The Contractor shall transmit analytical results of the demonstration samples to EPA in three stages. First, the raw data will be submitted by telephone or email as directed by the COR. These results will assist EPA in determining the efficacy of the new disposal or decontamination technologies. Second, the Contractor shall prepare a draft digital report. Third, after receiving comments from the COR, the Contractor shall then prepare the final analytical results which incorporate the COR's comments.

(5) The Contractor shall analyze for other pollutants of interest as directed by the COR. For example, PCBs in the U.S. is in short supply. The possibility exists that surrogates for PCBs may necessarily be used during PCB Disposal or Decontamination Demonstration. Should surrogates be used, the Contractor shall analyze samples for the surrogates. An example of a surrogate is trichlorobenzene.

B. Sample Media. The Contractor shall implement analytical methods suitable to the medium of interest. Examples of media include crankcase oil; mineral oil; solvents such as ethylene glycol; soils such as clay, sediment or sand; fly ash; and clinkers.

C. Sampling Kit.

(1) The Contractor shall provide sampling kits (as described in **Task 4**) for each demonstration suitable for the collection of samples of various media, but not limited to bulk solids such as soil; and bulk liquids such as fuel oil, solvents and water.

(2) The Contractor shall provide a sampling kit suitable for the collection and analysis of samples from porous surfaces (concrete, paint) and non-porous surfaces (metal).

D. For thermal technologies including incineration, the Contractor may be requested by the COR to observe the collection of samples from various process streams and obtain split samples for analysis by the Contractor.

E. The Contractor may be requested to provide personnel with appropriate experience and appropriate certificates to take the samples for any of the technologies and any of the media.

F. The Contractor shall submit a preliminary analysis to the COR for review and comment. Upon receipt of the comments the Contractor shall incorporate the comments into the final report.

Task 3. PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols

A. For thermal technologies including incineration, the Contractor may be requested by the COR to review the applicant's demonstration trial burn plan, to determine/plan the work schedule. Contractor should already be familiar with the process and equipment, from previous work with identical incinerator equipment.

B. For thermal technologies including incineration, the Contractor may be requested to determine if the applicants' stack emission sampling protocols to be used during the trial burn comply with EPA standards.

Task 4. Sampling Kit and Performance Evaluation (PE) Samples
The Contractor shall provide, at the direction of the COR, a sampling kit for EPA PCB Disposal or Decontamination technology evaluators. Sampling items are to be shipped in a cooler ranging in size from one (1) gallon to ten (10) gallons, as appropriate. Packing material must be provided and used as appropriate to minimize breakage of items.

At minimum, the following items shall be provided in the shipping cooler:

A. Traceability Log Forms (3 sheets minimum)
B. Quadruplicated bar codes in self-adhering format (3 sheets - 15 codes minimum per sheet). Traceability forms must accommodate bar codes and sample description.
C. Labels for sample containers to identify samples.
D. Disposable gloves (12 pairs minimum)
E. Wide mouth 100 ml. sampling jars, or 40 ml. vials "VOC" sampling type, or a mixture of jars and vials as specified by COR.
F. Spatulas, two medium size, metal
G. One fine tip marker, waterproof
H. Two writing pens, ball point or fine felt tip
I. "Blue ice" or chemical ice pack for sample preservation
J. Evidence tape, 2 feet in length
K. Shipping bill or air bill prepared for shipping samples to Contractor on overnight basis
L. "Zip locking" plastic bag to protect documents
M. Extra sampling containers in case of breakage or process anomaly
N. Paper towels, e.g. "Kimwipes"

Optional items below, which are required at times, specified by the COR, for specific projects:

O. One-liter jars for aqueous samples, quantity to be specified.
P. Wipe Sampling Kit:
   (1) Folded cotton gauze pad (e.g. 4"x4"), inserted in 100 ml wide mouth jar
   (2) Gauze pad saturated with solvent (e.g. hexane)
   (3) Template for wiping 100 centimeter square area or as specified
   (4) Template disposal or reusable, as specified
   (5) Quantity to be specified by COR
   (6) Solvent to be specified by COR
Q. Spoon or other instruments for sampling

Blind PE samples shall be prepared to evaluate laboratory(s) designated by applicants to analyze samples for the demonstration or for commercial operations. The PE sample(s) may be prepared using various media such as sand, oil (e.g., mineral oil dielectric fluid, MODEF), or water and at various concentrations as directed by the COR (e.g., Aroclor 1260 in MODEF, 10 g in flame sealed ampules; one between 15,000 – 18,000 ppm, one between 5 -10 ppm, and one between 0.5 - 2 ppm).

Task 5. Finalization of "PCB Guidance" and Response to Comments
Contractor shall update and finalize a document entitled "*Guidelines for Approval Applications and Demonstration Test Plans for PCB Disposal by Non-Thermal Alternative Methods, Thermal Alternative Methods, and Incineration*," also known as the "*PCB Guidance*." The document

discusses requirements for approval applications, demonstration test plans, demonstration test reports, and describes the approval process and how to conduct a demonstration. This document will help persons apply for disposal and cleanup PCB approvals from the EPA. Copies of the latest version of the guidance, will be provided by the COR to the contractor in Word.

Specifically, contractor will respond to external EPA comments on the PCB Guidance. Contractor shall collate the comments that come in from public comment and prepare a response to comment document. Contractor shall modify the PCB Guidance based on the response to comments and prepare a final version of the PCB Guidance which the COR will distribute to persons desiring a PCB disposal approval.

Task 6. Compiling Annual PCB Reports

At the direction of the COR, the Contractor shall:

1) Go through 2016 and 2017 annual reports (paper or electronic) that are provided by the COR and enter the facilities' data into the Excel spreadsheet file provided by the COR. The data to be entered will include the data described in the background section above.

2) In a document titled "PCB Annual Report Data Issues," provide to the COR a list of any missing data from any facilities, any facilities' whose annual reports the contractor was not able to decipher, and any facilities that reported data in previous years, but did not submit reports for subsequent years.

3) Update any graphs that are in the Excel file that the COR provides with the new data entered.

4) If requested by the COR, follow up with EPA Regional PCB staff or facilities to track down missing, incorrect, or illegible annual reports and make the additions or corrections to the excel spreadsheet and graphs.

Task 7. PCB Database Entry

Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1's database contains 757 entries and about 20 fields that are common to both databases. This task will have the Contractor perform the data entry from the Regional databases/spreadsheets into RCRAInfo, beginning with the Region 1 database.

The Contractor will enter as much of the PCB data from the Regional databases/spreadsheets into RCRAInfo, within the existing funding limits. Contractor will continue entering data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

Task 8. Potential Regulatory Changes

This is only a potential task, as the EPA has not decided to enact regulatory changes at this time, but EPA is discussing the potential to do this. Therefore, there is not currently funding dedicated to this task, and funding shall be assigned to this task on an as needed basis. The contractor will provide assistance to update the PCB Regulations to allow for additional extraction methods and provide various minor technical fixes which clarify the regulations. SW-846 methods for PCB extraction which are not allowed for under the 40 CFR Part 761 regulations, such as EPA Method 3541 (or Automated Soxhlet Extraction), should be compared to the existing method in the PCB Regulations – EPA Method 3540C (or Manual Soxhlet Extraction), to demonstrate equivalent or better extraction efficiencies from the newer method.

Data collection and analysis may be needed to justify a potential regulatory change for the allowance of alternate extraction methods. Only when directed, the Contractor shall assist EPA with:

- Preparing initial demonstration of lab capabilities (IDOC) for external multi-lab validation studies;
- Evaluating information, data and chromatograms collected from the IDOC, external multi-lab validation studies, and/or comparison studies;
- Compiling reports (e.g., analytical data report, QA/QC summary report, comparison study report);
- Maintaining records and materials generated during the data collection and analysis; and
- Collecting materials (e.g., references, the analytical data and QA/QC summary report, the comparison study report, the statistical analysis report, written articles or publications, response to public comments document) that support the regulatory change.

Other potential tasks include: drafting and/or reviewing an options paper, drafting and/or reviewing language for the regulatory change and the Federal Register, attending team meetings, and responding to public comments.

This work assignment relates to Tasks III, IV, and V of the current contract statement of work.

Deliverables

Deliverable	Schedule
Task 1: Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for review and acceptance.
Task 2: Sample Collection and Analysis	Within 2 weeks of receipt of samples, Contractor will provide draft results. Within 3 weeks of the receipt of the samples the Contractor shall provide a draft report of the chemical analysis. After the COR provides comments on the draft report the Contractor shall produce a final report within 30 days of the receipt of the COR's comments.

Task 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols	Within 20 days of receipt of a copy of the permit applicant demonstration plan, the Contractor will review and submit a summary report of the demonstration plan.
Task 4: Sampling Kit and Performance Evaluation (PE) Samples	Within 3 days of request by the COR, the Contractor will ship a sampling kit and /or performance evaluation samples to the demonstration site for use by EPA or its representative.
Task 5: Finalization of "PCB Guidance" and Response to Comments	Upon receipt of public comments, contractor shall have 30 days to prepare the response to comment document and another 20 days to incorporate the comments into the final "PCB Guidance."
Task 6: Compiling Annual PCB Reports	Within 4 weeks after receiving the necessary reports and Excel file from the COR, the Contractor shall update the Excel file. Within 4 weeks of receipt of comments from the Regions, the Contractor shall finalize the Excel file.
Task 7: PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.
Task 8: Potential Regulatory Changes	Within 2 weeks after receiving a draft document pertaining to the potential regulatory change, the Contractor shall review and submit edits and comments. Other tasks will be performed as directed by EPA COR.

Period of Performance

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2019.

Level of Effort

The approximate level of effort for this requirement is: **113 hours.**

EPA Contacts

Contracting Officer Representative

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-03

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2018 To 06/12/2019 Base Option Period Number 2	Technical Support for PCB Perm

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
The purpose of this Amendment is to add an additional 150 LOE hrs to the existing (Battelle EPW16017 WA 2-03 Task 7) 113 LOE hrs, bringing the total LOE hrs for WA 2-03 to 263 LOE hrs. The contractor shall provide a work plan within 30 business days.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2018 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Jennifer McLeod (Signature) (Date)	Branch/Mail Code: Phone Number: 703-308-8459 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

Statement of Work

Contract Number: EP-W-16-017
Work Assignment: 2-03
Amendment Number: 1
Title: Technical Support for PCB Permits and Document Development

Background

This project is a follow-on to WA 2-03. This WA 2-03 will address 8 on-going tasks in support of the PCB program and will be funded incrementally as funding becomes available.

We need to add hours to Task 7 to give the contractor enough time to fully complete the task. Due to Task 7 (the database entry) requiring not only the entry of data on existing sites in RCRAinfo, but also the creation of new sites into the database, we underestimated the level of effort (LOE) required to complete the task. This task will require 150 additional hours to complete.

Scope of Work

This WA will cover the following 8 PCB tasks, with those tasks marked as being initially funded in FY18:

Task 1 will involve task management, including work plan development. **This task will be funded in FY18.**

Task 2 will involve sample collection and analysis during on-site the PCB disposal or decontamination demonstrations.

Task 3 will involve PCB disposal and decontamination demonstration requiring review of sampling protocols, including stack emissions.

Task 4 will involve providing sampling kits and performance evaluation (PE) samples for PCB demonstrations.

Task 5 will involve updating the PCB Guidance that will help persons apply for PCB approvals for alternative technologies under 40 CFR §761. **This task will be funded in FY18.**

Task 6 will involve compiling the annual PCB reports into spreadsheets and graphs.

Task 7 will involve PCB notifications and approvals database entry into RCRAInfo. **This task will be funded in FY18.**

Task 8 will involve assisting the agency with making potential regulatory changes to the PCB regulations.

Tasks

Task 1. Task Management
The Contractor shall prepare and submit a work plan. Work under this task shall include participating in project update meetings/teleconferences, preparing the monthly progress reports and other task management.

When Tasks 2 and 4 are funded, this WA will require a Quality Assurance Project Plan (QAPP) and will require the use of TSCA CBI.
Quality Assurance Project Plans (QAPP) are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. In addition to abiding by its own Quality Management Plan that has been approved by EPA, all tasks that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

All major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The QAPP does not have to be submitted at the same time as the Technical and Financial Work Plan unless the environmental data activities covered under the QAPP must begin immediately. In many cases, planning for how to perform the work is needed before the QAPP can be prepared and submitted to EPA for approval. For example, under Task 2, when funded, the QAPP will be submitted when appropriate; however, no work involving the generation, collection, analysis and use of environmental data can begin until an EPA approved QAPP is in place.

NOTE: The tasks below represent all of the possible items that may be required by EPA to support the PCB cleanup and disposal program. Written technical direction will be provided by the COR which will specify the items and quantities needed for each permit.

Task 2. Sample Collection and Analysis

A. EPA will observe on-site the PCB Disposal or Decontamination Demonstrations and will collect samples and transfer the samples to the Contractor. The Contractor shall analyze the samples appropriately, as outlined below.

(1) For analysis of polychlorinated biphenyls (PCBs), the Contractor shall analyze samples for classes of PCB compounds called Aroclor. These compounds include but are not limited to the following:

Aroclor 1242	Aroclor 1260	Aroclor 1016
Aroclor 1254	Aroclor 1264	

(2) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify the 209 congeners of polychlorinated biphenyls.

(3) For analysis of PCBs, the Contractor shall provide analytical instrument capability and methodologies to analyze and to identify PCBs, separating and quantitating the identified PCBs in homologs from mono- to deca-chlorinated biphenyls. The analytical standard to be used shall be the Dry Color Manufacturer Association (DCMA) standard or equivalent.

(4) The Contractor shall transmit analytical results of the demonstration samples to EPA in three stages. First, the raw data will be submitted by telephone or email as directed by the COR. These results will assist EPA in determining the efficacy of the new disposal or decontamination technologies. Second, the Contractor shall prepare a draft digital report. Third, after receiving comments from the COR, the Contractor shall then prepare the final analytical results which incorporate the COR's comments.

(5) The Contractor shall analyze for other pollutants of interest as directed by the COR. For example, PCBs in the U.S. is in short supply. The possibility exists that surrogates for PCBs may necessarily be used during PCB Disposal or Decontamination Demonstration. Should surrogates be used, the Contractor shall analyze samples for the surrogates. An example of a surrogate is trichlorobenzene.

B. Sample Media. The Contractor shall implement analytical methods suitable to the medium of interest. Examples of media include crankcase oil; mineral oil; solvents such as ethylene glycol; soils such as clay, sediment or sand; fly ash; and clinkers.

C. Sampling Kit.

(1) The Contractor shall provide sampling kits (as described in **Task 4**) for each demonstration suitable for the collection of samples of various media, but not limited to bulk solids such as soil; and bulk liquids such as fuel oil, solvents and water.

(2) The Contractor shall provide a sampling kit suitable for the collection and analysis of samples from porous surfaces (concrete, paint) and non-porous surfaces (metal).

D. For thermal technologies including incineration, the Contractor may be requested by the COR to observe the collection of samples from various process streams and obtain split samples for analysis by the Contractor.

E. The Contractor may be requested to provide personnel with appropriate experience and appropriate certificates to take the samples for any of the technologies and any of the media.

F. The Contractor shall submit a preliminary analysis to the COR for review and comment. Upon receipt of the comments the Contractor shall incorporate the comments into the final report.

Task 3. PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols

A. For thermal technologies including incineration, the Contractor may be requested by the COR to review the applicant's demonstration trial burn plan, to determine/plan the work schedule. Contractor should already be familiar with the process and equipment, from previous work with identical incinerator equipment.

B. For thermal technologies including incineration, the Contractor may be requested to determine if the applicants' stack emission sampling protocols to be used during the trial burn comply with EPA standards.

Task 4. Sampling Kit and Performance Evaluation (PE) Samples

The Contractor shall provide, at the direction of the COR, a sampling kit for EPA PCB Disposal or Decontamination technology evaluators. Sampling items are to be shipped in a cooler ranging in size from one (1) gallon to ten (10) gallons, as appropriate. Packing material must be provided and used as appropriate to minimize breakage of items.

At minimum, the following items shall be provided in the shipping cooler:

A. Traceability Log Forms (3 sheets minimum)
B. Quadruplicated bar codes in self-adhering format (3 sheets - 15 codes minimum per sheet). Traceability forms must accommodate bar codes and sample description.
C. Labels for sample containers to identify samples.
D. Disposable gloves (12 pairs minimum)
E. Wide mouth 100 ml. sampling jars, or 40 ml. vials "VOC" sampling type, or a mixture of jars and vials as specified by COR.
F. Spatulas, two medium size, metal
G. One fine tip marker, waterproof
H. Two writing pens, ball point or fine felt tip
I. "Blue ice" or chemical ice pack for sample preservation
J. Evidence tape, 2 feet in length
K. Shipping bill or air bill prepared for shipping samples to Contractor on overnight basis
L. "Zip locking" plastic bag to protect documents
M. Extra sampling containers in case of breakage or process anomaly
N. Paper towels, e.g. "Kimwipes"

Optional items below, which are required at times, specified by the COR, for specific projects:

O. One-liter jars for aqueous samples, quantity to be specified.
P. Wipe Sampling Kit:
   (1) Folded cotton gauze pad (e.g. 4"x4"), inserted in 100 ml wide mouth jar
   (2) Gauze pad saturated with solvent (e.g. hexane)
   (3) Template for wiping 100 centimeter square area or as specified
   (4) Template disposal or reusable, as specified
   (5) Quantity to be specified by COR
   (6) Solvent to be specified by COR
Q. Spoon or other instruments for sampling

Blind PE samples shall be prepared to evaluate laboratory(s) designated by applicants to analyze samples for the demonstration or for commercial operations. The PE sample(s) may be prepared using various media such as sand, oil (e.g., mineral oil dielectric fluid, MODEF), or water and at various concentrations as directed by the COR (e.g., Aroclor 1260 in MODEF, 10 g in flame

sealed ampules; one between 15,000 – 18,000 ppm, one between 5 -10 ppm, and one between 0.5 - 2 ppm).

Task 5. Finalization of "PCB Guidance" and Response to Comments
Contractor shall update and finalize a document entitled "*Guidelines for Approval Applications and Demonstration Test Plans for PCB Disposal by Non-Thermal Alternative Methods, Thermal Alternative Methods, and Incineration*," also known as the "*PCB Guidance.*" The document discusses requirements for approval applications, demonstration test plans, demonstration test reports, and describes the approval process and how to conduct a demonstration. This document will help persons apply for disposal and cleanup PCB approvals from the EPA. Copies of the latest version of the guidance, will be provided by the COR to the contractor in Word.

Specifically, contractor will respond to external EPA comments on the PCB Guidance. Contractor shall collate the comments that come in from public comment and prepare a response to comment document. Contractor shall modify the PCB Guidance based on the response to comments and prepare a final version of the PCB Guidance which the COR will distribute to persons desiring a PCB disposal approval.

Task 6. Compiling Annual PCB Reports
At the direction of the COR, the Contractor shall:

1) Go through 2016 and 2017 annual reports (paper or electronic) that are provided by the COR and enter the facilities' data into the Excel spreadsheet file provided by the COR. The data to be entered will include the data described in the background section above.

2) In a document titled "PCB Annual Report Data Issues," provide to the COR a list of any missing data from any facilities, any facilities' whose annual reports the contractor was not able to decipher, and any facilities that reported data in previous years, but did not submit reports for subsequent years.

3) Update any graphs that are in the Excel file that the COR provides with the new data entered.

4) If requested by the COR, follow up with EPA Regional PCB staff or facilities to track down missing, incorrect, or illegible annual reports and make the additions or corrections to the excel spreadsheet and graphs.

Task 7. PCB Database Entry
Several Regions have either an *Access* database or *Excel* spreadsheet containing their PCB notifications and PCB approvals data. Since EPA is moving to a national PCB database in *RCRAInfo*, there is a need to re-enter all the data from the Regional databases/spreadsheets into *RCRAInfo*. In particular, Region 1's database contains 757 entries and about 20 fields that are common to both databases. This task will have the Contractor perform the data entry from the Regional databases/spreadsheets into RCRAInfo, beginning with the Region 1 database.

The Contractor will enter as much of the PCB data from the Regional databases/spreadsheets into RCRAInfo, within the existing funding limits. Contractor will continue entering data from the Region 1 database as well as other Regional database/spreadsheets as they become available. Contractor will enter the data manually (i.e., typing) and perform a data entry quality assurance check (i.e., every field entered for every site will be double checked for correctness by a separate individual).

Task 8. Potential Regulatory Changes

This is only a potential task, as the EPA has not decided to enact regulatory changes at this time, but EPA is discussing the potential to do this. Therefore, there is not currently funding dedicated to this task, and funding shall be assigned to this task on an as needed basis. The contractor will provide assistance to update the PCB Regulations to allow for additional extraction methods and provide various minor technical fixes which clarify the regulations. SW-846 methods for PCB extraction which are not allowed for under the 40 CFR Part 761 regulations, such as EPA Method 3541 (or Automated Soxhlet Extraction), should be compared to the existing method in the PCB Regulations – EPA Method 3540C (or Manual Soxhlet Extraction), to demonstrate equivalent or better extraction efficiencies from the newer method.

Data collection and analysis may be needed to justify a potential regulatory change for the allowance of alternate extraction methods. Only when directed, the Contractor shall assist EPA with:

- Preparing initial demonstration of lab capabilities (IDOC) for external multi-lab validation studies;
- Evaluating information, data and chromatograms collected from the IDOC, external multi-lab validation studies, and/or comparison studies;
- Compiling reports (e.g., analytical data report, QA/QC summary report, comparison study report);
- Maintaining records and materials generated during the data collection and analysis; and
- Collecting materials (e.g., references, the analytical data and QA/QC summary report, the comparison study report, the statistical analysis report, written articles or publications, response to public comments document) that support the regulatory change.

Other potential tasks include: drafting and/or reviewing an options paper, drafting and/or reviewing language for the regulatory change and the Federal Register, attending team meetings, and responding to public comments.

This work assignment relates to Tasks III, IV, and V of the current contract statement of work.

Deliverables

Deliverable	Schedule
Task 1: Task Management	Within 30 days of issuance of Work Assignment Amendment, the Contractor shall submit a Work Plan for review and acceptance.

Task 2: Sample Collection and Analysis	Within 2 weeks of receipt of samples, Contractor will provide draft results. Within 3 weeks of the receipt of the samples the Contractor shall provide a draft report of the chemical analysis. After the COR provides comments on the draft report the Contractor shall produce a final report within 30 days of the receipt of the COR's comments.
Task 3: PCB Disposal and Decontamination Demonstration Requiring Review of Sampling Protocols	Within 20 days of receipt of a copy of the permit applicant demonstration plan, the Contractor will review and submit a summary report of the demonstration plan.
Task 4: Sampling Kit and Performance Evaluation (PE) Samples	Within 3 days of request by the COR, the Contractor will ship a sampling kit and /or performance evaluation samples to the demonstration site for use by EPA or its representative.
Task 5: Finalization of "PCB Guidance" and Response to Comments	Upon receipt of public comments, contractor shall have 30 days to prepare the response to comment document and another 20 days to incorporate the comments into the final "PCB Guidance."
Task 6: Compiling Annual PCB Reports	Within 4 weeks after receiving the necessary reports and Excel file from the COR, the Contractor shall update the Excel file. Within 4 weeks of receipt of comments from the Regions, the Contractor shall finalize the Excel file.
Task 7: PCB Database Entry	Upon receipt of databases from the Regions, the Contractor shall enter the data into RCRAInfo within 10 days.
Task 8: Potential Regulatory Changes	Within 2 weeks after receiving a draft document pertaining to the potential regulatory change, the Contractor shall review and submit edits and comments. Other tasks will be performed as directed by EPA COR.

Period of Performance

This work assignment will start on the date of the contracting officer's signature and extend through June 13, 2019.

Level of Effort

The approximate level of effort for this requirement is: **113 hours.**

EPA Contacts

Contracting Officer Representative

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Alternate Contracting Officer Representative
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2777 S. Crystal Drive
Room S-6341
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019	Support for Formaldehyde
	Base Option Period Number 2	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-04. Contractor shall provide work plan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2019 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Robert Courtnage (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1081
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

Battelle
Contract Number: EP-W-16-017

Work Assignment Number: 2-04

Title: Support for Formaldehyde Compliance Guides and Other Outreach

I. Purpose and Background

To provide EPA ongoing technical support to develop guidance materials for the Formaldehyde Emission Standards for Composite Wood Products regulations. This project is a continuation of work assignment (WA) 0-04 under contract EP-W-16-017. This WA continues the work initiated in WA 0-04 under contract EP-W-16-017. No work shall be duplicated. Note this change is an increase in level of effort (LOE) hours only.

Title VI of the Toxic Substances Control Act (TSCA Title VI) establishes formaldehyde emissions for composite wood products and requires EPA to promulgate regulations to ensure compliance with these emission standards. EPA has promulgated regulations for TSCA Title VI which have requirements for manufacturers (including importers), fabricators and laminators of composite wood products. Other entities, such as retailers, wholesalers, and distributors are required to sell, supply, or offer for sale, only composite wood products that are compliant with the regulations. The regulations also establish a third-party certification program for composite wood products. The contactor shall translate and revise, as needed, small entity compliance guides, as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and other rule compliance-related materials as directed by the contracting officer representative (COR). The contactor shall provide, as directed by the COR, technical and graphical support for final rule implementation outreach including materials for the EPA Formaldehyde Resource Directory (website).

II. Scope of Work:

For all tasks, the contractor shall:

Task 1: Develop a Work Plan

The contractor shall prepare and submit a technical and financial work plan in accordance with the contract requirements.

Task 2: Develop Language Translations for Small Entity Compliance Guides

For each of the final English language Compliance Guides including: 1) third-party certifiers and accreditation bodies, 2) panel producers, 3) importers, distributors and retailers, and 4) fabricators (including laminators), provide up to 3 language translations, as needed and as directed by the COR. The final Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: Provide Technical Support for EPA Formaldehyde Resource Directory (website)

The contractor shall provide support, as directed by the COR, for technical and graphical materials related to the Formaldehyde Emission Standards from Composite Wood Products final rule implementation and compliance including materials for the EPA Formaldehyde website.

III. Deliverables:

For all deliverables, the contractor shall:

Task 1: Submit a work plan within 30 working days of receipt of work assignment.

Task 2: Provide the COR revised written translations, in a language directed by the COR, of the four English language Compliance Guides within 30 working days after being tasked by the COR. The files shall be professional print-ready files and suitable for EPA web publication. The final translated Compliance Guides must be in compliance with section 508 of the Rehabilitation Act.

Task 3: As directed by the COR provide graphics, displays, forms, etc., for print or for the EPA Formaldehyde website.

A work plan is required.

A QA/QC plan is not required since no data collection applies.

CBI does not apply.

This work assignment relates to Tasks III, and IV of the current Statement of Work (SOW) of the contract. The work assignment shall start upon the Contracting Officer's signature and extend to June 12, 2019.

The Approximate Level of Effort: 135 hours

Contracting Officer Representative:
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courtnage.robert@epa.gov
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Deputy Contracting Officer Representative:
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202-564-1208

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Clean Water Act

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-05; Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Brian Schnitker (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-0838 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)		Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

Contract No. EP-W-16-017
Work Assignment 2-05

TITLE: **Statistical Support for Clean Water Act**

Contracting Officer Representative
Brian Schnitker, OW/OST/EAD
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Alternate Contracting Officer Representative
Paul Shriner, OW/OST/EAD
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Period of Performance: work assignment issuance through June 31, 2019

This work assignment relates to Task I Collection of Data, Task II Data Analysis, and to a lesser extent, Task III Technical Program Support - General Support, of the current Statement of Work (SOW) of the contract. In particular, the work assignment will provide support for activities authorized by the Clean Water Act. The contractor shall provide support in areas including statistical analysis of laboratory data, statistical review and comment, and statistical documentation. A work plan is required (see Task 1).

This Work Assignment will provide follow-on statistical support for the NY/NJ Harbor and Super Storm Sandy Study (Task 10 in WA 4-4 under Contract EP-W-09-024) and monitoring support (Task 13 in WA 4-4). The WA also will provide statistical support for designing one or more surveys of POTWs (i.e., a new project). The WA's tasks do not duplicate statistical support previously tasked elsewhere.

Confidential Business Information: EPA will not provide any data/information that are Confidential Business Information (CBI) for use in the work assignment.

I. BACKGROUND

A. NY/NJ Harbor Statistical Analyses (Task 3)

The majority of the work for this task has been completed as of May 2018. The language has been retained in this work assignment to support follow on work that comes up as the work is reviewed, such as revisions or providing any data found to be missing.

For its assessment of post-SSS conditions in the summer of 2013, EPA-Region 2 collected samples from sites selected from the previous 2008 REMAP probability-based sampling design. Starting on October 28, 2012, Super Storm Sandy (SSS) arrived offshore of NY and NJ with hurricane force winds, heavy rainfall, and a tidal surge that damaged or destroyed approximately 500,000 homes and businesses, caused breaches in the barrier islands, and inundated Superfund sites and wastewater

treatment facilities. Resultant flooding, as well as sustained power outages, released and/or redistributed contaminants. The NY/NJ Harbor complex (Upper Harbor, Lower Harbor, Newark Bay and Jamaica Bay), as well as Barnegat Bay in NJ, and freshwater tributaries along the coast were the USEPA-Region 2 water resources that were particularly impacted.

Using EPA's consolidated database, the contractor shall use the data from the 1993/4, 1998, 2003, 2008 and 2013 Harbor samples and the freshwater biological sampling results to statistically compare and assess pre- to post-SSS sediment conditions and any trends that may be present. None of the data are CBI.

It should be noted that much of this task has been completed and EPA does not expect a significant amount of work to be performed on this task. Time should be allotted, however, to address any issues or refinements of the final report and working with EPA to complete the upload of the database to STORET.

The study objectives are as follows:

1. Objective 1 (NY/NJ Harbor sediment survey)

   Determine whether there are statistical differences in the areal extent and levels of sediment contaminants, sediment toxicity, and condition of benthic macroinvertebrate assemblages in the NY/NJ Harbor between 2008 and 2013.

2. Objective 2 (Intensive survey of 4 WWTP receiving waters)

   Conduct bacteriological water and sediment contaminant sampling in the waterbodies that receive the discharge from the following wastewater treatment plants (WWTPs) or pump stations in NY and NJ. The current data from these WWTPs will be compared to standards and previously collected data.

   a. Bay Park WWTP
   b. Middlesex County Utilities Authority, NJ pump stations (2)
   c. Passaic Valley Sewerage Commission
   d. Yonkers WWTP

3. Objective 3 (Freshwater biological sampling)

   Determine whether there are statistical differences in the condition of benthic macroinvertebrate communities in the freshwater portions of NJ Water Management Areas (WMAs) 4, 7, 9, and 12 by comparing current results with historical data.

B. Statistical Design of POTW Study (Task 4)

Over the last 50 years, the amount of nitrogen and phosphorus pollution entering the nation's waters has escalated dramatically. The excess levels of nutrients have degraded drinking water quality and environmental water quality. Nutrients have the potential to become one of the costliest

and most challenging environmental problems we face. States need to be able to respond to local water quality needs, and will need a variety of tools and resources to successfully achieve effective and sustained progress towards nutrient reductions.

This work assignment provides support to further EPA's commitment to partnering with states and industry, and collaborating to make greater progress in accelerating the reduction of nutrient loads to the nation's waters. The Office of Water is collecting data to evaluate the nutrient removals and related technology performance by all types of sewage treatment plants, wastewater treatment plants (WTPs), Publicly Owned Treatment Works (POTWs). The Office of Science and Technology, Engineering and Analysis Division, will be leading the effort by commencing a National Study of Nutrient Removals and Secondary Technology, or the "National Study". This study is a comprehensive data collection effort to be conducted in phases including a screener survey (conducted as a census) and a detailed technical survey, to be followed by one to two years of sampling and monitoring by select facilities to assess in-plant performance. The effort fills numerous data gaps not addressed by other existing sources of information, including the Clean Water Action Needs Survey (CWNS), existing monitoring data obtained from EPA's Integrated Compliance Information System (ICIS), and the existing literature. The survey would help: establish baseline loads of nutrients to watersheds, identify technologies in place, assess the performance of these technologies, identify operational and management practices that allow wastewater treatment plants to maximize the effectiveness of their existing technologies, and collect cost and labor information on these operational and management practices. The information would inform basic policy regarding nutrient contributions from municipalities; support states with information needed to set reasonable load-reduction goals; enable states to reduce loadings through a combination of strengthened permits and reduction measures; provide information useful to treatment plant owners and operators through forums, peer to peer sharing, and operator training.

C. *Statistical Analysis of Monitoring Data (Task 5)*

Throughout the year (i.e., period of performance), EPA occasionally needs statistical support on a quick turn-around basis for initiatives under the Clean Water Act. Such projects tend to focus on a relatively small issue that can be addressed with relatively low effort within 2-4 weeks. EPA will identify the datasets and analysis objectives related to monitoring data. None of the data will be CBI.

For each task listed below, the contractor shall:

Task 1: Work Plan and Monthly Progress Report – para 1-2, page 4

The contractor will provide a work plan that describes the support that will be provided; identifies deliverables; and identifies potential problems that may arise in completing this work assignment on schedule and within budget. The work plan shall individually identify the estimated LOE and costs separately for each of the tasks on the WA.

The contractor shall provide overall work assignment management and interface with the EPA COR.

TASK 1 – DELIVERABLES	
Deliverable	**Due Date**
Work plan	• Due 30 calendar days following receipt of Work Assignment.
Interface with EPA COR	• As needed

In addition, the contractor shall provide a monthly progress report containing, at a minimum, the following information:

- Memo # and date
- Date due
- EPA technical contact
- Contractor lead staff
- Topic
- Hours allocated per task
- Used this month per task
- Cumulative used per task

Task 2: Quality Assurance- para 3-12, pages 4-8

Quality Assurance Project Plans are required under the Agency's Quality Assurance Policy CIO-2105, formerly EPA Order 5360.1A2 and implementing guidance CIO-2105-P-01-0. All projects that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of the work.

QA Project Plan Requirements

EPA policy requires that an *approved* Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental information or data. In addition to abiding by its own Quality Management Plan, the contractor shall adhere to the following requirements for:

- Task 3 (NY/NJ Harbor support), the contractor shall adhere to "Quality Assurance Project Plan: Post-Super Storm Sandy (SSS) Water Quality Monitoring in Coastal New Jersey and New York ("SSS QAPP")." Unless already provided to EPA, the contractor shall provide the EPA COR with copies of the QAPP certification page signed by the contractor's QAO, the contract's project manager, the work assignment leader, and any other person providing substantial support to the task.
- Task 4 (National Study), the contractor shall adhere to a project-level QAPP or "pQAPP," and upon receiving technical direction, shall develop an sQAPP or amend the pQAPP for the statistical activities described in Task 4. Task 4 specifies the additional QAPP related activities that may occur during this WA period of performance. If the EPA COR provides technical direction that QAPP revisions are determined to be necessary, the contractor shall submit a revised QAPP, including the revision summary, within 10 to 15 work days, depending on the complexity of the changes. When preparing this revised version, the contractor shall ensure that it is written in an active voice and shall include a version history page that summarizes changes made. The contractor shall also provide the revised QAPP in track changes and compare document. The contractor also shall provide EPA with copies of any modified SOPs or checklists. The EPA COR shall formally accept these for project records by providing a signature page that includes the EPA COR's and EPA QAO's signatures. EPA shall review the revised QAPP and provide the contractor with written approval or comments. The contractor shall provide a final revised QAPP responding to any EPA comments within 10-15 work days of receiving EPA's comments.
- Task 5 (Quick Response), the contractor shall adhere to the QAPP.

Additional QA Documentation Required

In addition to the QAPP requirements described above and already required by Task 2, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used consistent with the approved QAPP.

For any QAPP developed under this work assignment, the contractor shall verify that the QAPPs:

- Addresses all activities identified in this PWS that involve the **generation** (including field studies, laboratory studies, and modeling output), **collection** (including surveys, literature searches, and third party data), **evaluation** (including data inspection and management, review, assessment, and validation), **analysis** (including statistical, engineering, and economic analysis and testing, evaluation, and validation of methods and models) **and use of data** to support EPA decisions, regulations, policy, publications

or tools (including effluent guidelines, methods, criteria, standards, environmental assessments, and models, tools, or reports disseminated by EPA to assist other organizations in implementing environmental programs). Examples of data include, but are not limited to, wastewater sample analysis results, flow measurements or data, facility questionnaire data, economic data, field sample data and laboratory analyses results, use of models, secondary data (including sources and the acceptance criteria), any software and database management requirements and any other relevant work that might affect the quality of the data. Note that QAPPs are also required for the development or revision of models and software that support the generation, collection, evaluation, analysis or use of data. For example, when existing models are used as a tool to generate or evaluate data, the project QAPP must describe the model, how it shall be used, and how the model output shall be evaluated to ensure it meets the overall quality objectives for the project. However, development or revision of new models also must be supported by a QAPP that describes the objectives for the model, the quality criteria that shall be applied to the model, and the procedures for evaluating whether the model meets those criteria.

- Provides enough detail to clearly describe objectives of the project supported by the work assignment; the type of data to be collected, generated, or used under this work assignment to support the project objectives; the quality objectives needed to ensure that these shall support the project objectives; and the quality assurance and quality control activities to be performed to ensure that any results obtained are documented and are of the type, quality, transparency, and reproducibility needed.
- Includes specific performance criteria and measures that shall be used to verify that data generated, collected or used in this work assignment meet those criteria. If a database or other electronic tool (e.g., model, spreadsheet, etc.) shall be created for the project, the QAPP must describe how the database or electronic tool shall be documented (e.g., data element dictionary, user manual, SOP, or other means appropriate for the project), the controls to ensure accurate data entry (when for instance data from another source are manually entered into the database), data transfer (when data are transferred from one electronic medium to another), or data merging (when data from multiple databases or electronic media are merged into a single database).
- Explicitly references tools, such as SOPs, checklists, and guidelines that the contractor shall use in the project to document data quality. The QAPP must include the tools as attachments for EPA's review and acceptance.
- Addresses the following general questions:
  - What is the objective/goal of this effort?
  - What are the roles and responsibilities of staff who shall support this project, and how to they relate to the specific key steps?
  - What training and competency requirements are necessary for key personnel that shall support the project?
  - If models shall be used to support the project, what are these models, why have they been selected, and how shall they be validated, documented, and used?
  - What are the SOPs, tools and checklists that shall be used?

- **Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed without an approved QAPP (or addendum) in place 50 work days after submission of the contractor's work plan.**

- Under no circumstances shall field sampling or laboratory analysis activities be conducted prior to receipt of an approved work plan.
- Any non-sampling/non-analytical work that involves the generation, collection, evaluation, analysis, or use of environmental data that is initiated prior to approval of the contractor's QAPP must be performed in accordance with the approved QAPP. (The QAPP requirements must be applied retroactively to this period that lasts no more than 50 work days from submission of the contractor's work plan).

Data Quality Act/Information Quality Guidelines Requirements
The Data Quality Act (also known as the Information Quality Act) requires EPA to ensure that influential information disseminated by the Agency is sufficiently transparent in terms of data and methods of analysis that the information is capable of being substantially reproduced. To support compliance with these data transparency/data reproducibility requirements, EPA plans to include QAPPs as part of any rulemaking record documentation to be made available to the public.

Information contained in the approved QAPP must be transparent and reproducible and meet the requirements of the Data Quality Act for influential information. EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency* (EPA/260R-02-008, October 2002), referred to as "EPA's Information Quality Guidelines," describe EPA procedures for meeting Data Quality Act requirements. Section 6.3 of EPA's Information Quality Guidelines indicate that "especially rigorous robustness checks" should be applied in circumstances where quality-related information cannot be disclosed due to confidentiality issues. Where applicable, the contractors should indicate which results were obtained using the tools (SOPs, checklists, and guidelines) that the contractor designates as confidential so that the EPA COR can easily identify the areas that shall require rigorous robustness checks and document that those checks have been performed.

Additional QA Documentation Required
In addition to the QAPP requirements described above, all major deliverables (e.g., Memoranda, Technical Support Documents, Study Reports, Study Plans, etc.) produced by the contractor under this work assignment must include a discussion of the QA/QC activities that were or shall be performed to support the deliverable. For example, a Technical Support Document or Study Report must include a clear discussion of the quality management strategies that were employed to control and document the quality of data generated and used.

The contractor also shall provide EPA with monthly reports of QA activities performed during implementation of this work assignment. For each of Tasks 3 to 7, these monthly QA reports shall identify QA activities performed to support implementation of this work assignment, problems encountered, deviations from the QAPP, and corrective actions taken. If desired, the contractor may include this as a part of the contract-required monthly financial/technical progress report. In addition, the contractor shall provide timely notification to the EPA COR of any QA problems that may affect the conduct of the tasks, with recommendations for corrective actions.

TASK 2 – DELIVERABLES	
Deliverable	**Due Date**
Signed pQAPP certification pages for SSS (Task 3) and, if provided, project-level National Study (Task 4)	Any new assigned personnel to the projects, who will provide substantial support, have 5 work days from start of the assignment.
pQAPP and/or sQAPP for statistical support for National Study	The first draft is due 15 work days after receiving technical direction. Revisions and final version are due in 1-10 work days, depending on complexity, as specified in technical direction.
QA/QC section in all major deliverables	Per schedule for major deliverables
QA/QC progress reports	One per month per task (may be included in progress report)
Email identifying QA/QC issues and recommended action	Timely notification when EPA COR input is required for proceeding on task.

Task 3: Finalizing Statistical Analysis of Sediment Data NY/NJ Harbor System- para 13, page 8

As noted in the Background section, most of the work on this task has been completed, so only a few minor items need to be addressed. They are as follows:

- Complete necessary final report edits by July 30, 2018 to address EPA's remaining comments. Ensure the report is a stand-alone document (links currently depend on the "Box" document platform, which cannot be used or hosted by EPA).
- Provide supporting documentation of data analyses (if not contained in the final report) by July 30, 2018.
- Schedule a teleconference (June 2018) to determine what specific data have been uploaded to WQX/STORET and what remains to be uploaded. Some analyses were uploaded were in aggregate (e.g. total PCBs) but raw data also need to be uploaded. Complete upload by July 15, 2018.
- Clarify, correct, and/or add text/analyses if necessary.

Task 4. National Study- para 14, pages 8-12

The National Study is conducted in phases, some of which include timelines beyond the control of either the COR or the contractor (for example, when software acquisition is delayed or where approvals to conduct a survey are pending), and which may extend beyond this WA's period of performance. Further, EPA recognizes the contractor cannot recommend specific analytical approaches and methodologies, nor delineate pros and cons of the different approaches until after the final response rate is known and completeness of the collected data has been established. For these reasons, for planning purposes, the LOE for this Task 4 is estimated at 500 hours. This LOE does not include other tasks in this work assignment. **The contractor shall not proceed with this task 4 and each subtask below until the COR issues**

technical direction. Under this work assignment, the contractor will provide support to EPA with the following:

a) Assess the POTW characterization database resulting from the attributes screener (the census) for non-response bias, perform appropriate certainty band limit tests (such as T test or F tests); perform sensitivity and outlier tests, identify follow-up recommendations, and similar activities. The contractor shall provide a draft SOP for data management and statistical approaches for use with the POTW characterization database. For planning purposes, the contractor shall assume two scenarios of response rates to the census: 2000 POTW responses out of 18600 possible responses (roughly 10 % response rate), and 9000 POTW responses out of 18600 possible responses (a 50 % or better response rate). As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment.

b) Assess the database again after completion of any follow-up activities, and provide a Data Management Concept Memo that provides the specific statistical techniques and approaches that can be used with the POTW characterization data, along with pros and cons of each approach. As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment.

c) In the event the census is not fielded, the COR will provide a partial POTW baseline characterization database that consists of data obtained from CWNS, NPDES-ICIS, and voluntarily submitted performance data from POTWS. The contractor shall assess this database for response bias, perform appropriate certainty band limit tests (such as T test or F tests), perform sensitivity and outlier tests, identify geographical representativeness of the dataset, identify follow-up recommendations, and similar activities. For planning purposes, assume the database will contain 100 to 200 POTW responses (representing 1 % of the 18,600 possible responses). As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment. Note this subtask will not occur if subtasks a) is conducted.

d) In the event of unacceptably low response rates to the census, EPA has developed a sampling frame for another project under Contract EP-W-09-024, that needs to be statistically evaluated and possibly modified for use in the National Study. The contractor shall evaluate the sample frame provided by the COR, which includes the Targeted National Sewage Sludge Survey (TNSSS) bio-solids sample frame. (EPA will provide documentation and databases from the bio-solids sample frame used in Contract EP-C-05-030 and WA 4-4 in Contract EP-W-09-024 and the added information that compiled under a separate effort.) Upon written technical direction to assess the TNSSS for this purpose, the contractor will provide a written assessment of the sample frame for the stated purposes, the ease of using it to develop a sampling plan, identify any deficiencies, and recommend actions to remedy them. As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment.

e) Provide a Technical Survey Development Concept Memo based on the final technical criteria identified by the COR, which will identify cohorts and sampling frames from the population provided by the census. These represent the cohorts for a second survey, a detailed technical survey. For example, the COR may identify size, population, and treatment technology type as the criteria, and the contractor shall evaluate the POTW characterization database for such use. As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment. For planning purposes, this subtask will not occur until after a final POTW characterization database has been developed and evaluated under one of the subtasks a) through d) above.

f) Memorandums documenting the selected stratification developed for the Technical Survey. As part of this subtask the contractor will provide QA procedures for the analyses and evaluation of the data, which must be attached to the QAPP under Task 2 for this work assignment.

g) Design statistical sampling plans for the POTW study. The contractor shall design these plans to achieve EPA's goals and objectives for statistical inferences about the selected populations. See the first and second FR notices and the supporting statement, all in the public record, for details. The contractor shall estimate and technically evaluate the precision associated with the sampling plans, the subpopulations in the strata, and post-stratification. The contractor also shall include recommendations in the sampling plans for identifying and handling anomalies. The contractor shall estimate the burden and costs for the respondents and EPA of implementing the sampling plans. The contractor shall attend up to four 1-day meetings to discuss study objectives at EPA HQ and participate in weekly teleconferences discussing objectives and progress. For planning purposes, this activity will not commence until 2019 at the earliest.

h) Provide review and responses to any statistical review, comment, and analysis of survey designs (e.g., comments from industry). The contractor shall technically evaluate whether the survey designs will achieve EPA's objectives and allow for statistical inferences from the results. Provide review and comment on drafts of survey instruments, related letters, and supplemental information to ensure that EPA is collecting the necessary information to execute the sampling plan. The contractor shall evaluate each survey instrument for clarity, content, design, format, structure, and consistency with EPA's objectives.

i) Draft portions of statistical documentation of ICR packages that shall be consistent with EPA objectives, the Paperwork Reduction Act, Executive Order 12866, and Office of Management and Budget requirements.

j) Draft a final report that contains an explanation of the QA performed to determine the usability, transparency and reproducibility of the data. For planning purposes, for this WA period of performance, assume a POTW characterization database resulting under subtask a, b, c, or d. Do not assume a second technical database is developed during this period of performance.

The contractor shall prepare the following specific deliverables in parallel with the QA tasks identified under task 2 of this WA. The contractor shall report the technical progress, LOE, and costs of Task 4 separately from the other tasks on this work assignment. Accordingly, the following deliverables are identified as Task 4 deliverables.

Task 4 Deliverables	
Deliverable	**Deadline**
Addendum to SQAPP	• 10 days after notification by the COR via Technical Direction (TD) that an addendum to the SQAPP is needed.
Revisions to S/PQAPP based on EPA feedback	• 7 days after receipt of EPA feedback from COR via TD.
Final SQAPP for this Work Assignment	• 5 days after EPA feedback from COR via TD.
PQAPP/SQAPP progress reports	• Monthly.

The contractor shall prepare the following specific subtask deliverables.

Task 4 – Subtask Deliverables		
Subtask	**Deliverable**	**Due Date**
a	Memo with sample frame recommendations	5 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency.
b	Sampling plans	15 work days after receiving technical direction. Revisions within 2-15 work days depending on complexity and urgency, per technical direction. EPA COR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
	Meetings	EPA COR will schedule dates and times upon consultation with the contractor.
	Teleconferences	EPA COR will schedule dates and times upon consultation with the contractor, and cancel as appropriate.
c	Memo with reviews	5-10 work days depending on complexity and urgency, per technical direction.
e	Draft ICR sections and supporting documents	5-10 work days depending on complexity and urgency, per technical direction.
f	Memo, QA	5-10 work days depending on complexity and urgency, per technical direction.
g	Sampling Plan	5-10 work days depending on complexity and urgency, per technical direction.

Task 4 – Subtask Deliverables		
Subtask	**Deliverable**	**Due Date**
h	Technical Memo/Response	5-10 work days depending on complexity and urgency, per technical direction.
f	Technical progress, LOE, and cost reports	Monthly with progress report.

Task 5 Quick Response Statistical Analyses of Monitoring Data-para 15, page 12

The contractor shall not proceed with this task until the EPA COR issues technical direction. The contractor shall determine and apply appropriate statistical procedures and methodologies in analyzing and interpreting monitoring data. The types of methodologies shall include, but not be limited to: nonparametric statistics, multivariate analysis, regression analysis, maximum likelihood estimation, analysis of variance, time series, categorical data analysis, survey statistics, inferential statistics, spatial analysis, survival analysis, statistical meta-analysis, and graphical analysis. The contractor shall clearly specify the methods, procedures, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document the reasons for selecting particular procedures, methodologies, and assumptions; and alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. EPA will review all outputs and provide agency input/changes. The contractor shall incorporate the changes specified by EPA. The contractor shall track and report the technical progress, LOE, and costs separate from the other tasks on this work assignment.

Task 5 – DELIVERABLES	
Deliverable	**Due Date**
Statistical Analysis (memo)	Within 1-10 work days, depending on complexity, as specified in technical direction. Revisions within 1-5 work days, depending on complexity, as specified in technical direction.
Programs and input data files	Within 5 work days after receiving technical direction.
Technical progress, LOE, and cost reports	Monthly with progress report.

II. TRAVEL: The contractor shall attend up to three 1-day meetings in Washington, DC in support of Task 4.

III. PERIOD OF PERFORMANCE: This work assignment will start on the date of the contracting officer's signature and extend through the following 365 days.

IV. APPROXIMATED LEVEL OF EFFORT: 650 hours (500 for Task 4)

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-05

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2018 To 06/12/2019	Clean Water Act
	Base Option Period Number 2	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
The purpose of this amendment is to correct a typo that occurred in the original work plan approval. Cost: $85,065; Fee: $3,135; Cost Plus Fee: $88,200. The contractors are to submit a work plan to reflect the correct numbers.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2018 To 06/12/2019		0
This Action:		0
Total:		0

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Brian Schnitker (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0838 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-05

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021 Base Option Period Number 2	Clean Water

Contractor: Battelle Memorial Institute

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
The purpose of this amendment is to reduce the LOE hours down to 80. Per the Office of Water we will be closing out this work assignment.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2021 Cost/Fee: LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee LOE:

Cumulative Approved: Cost/Fee LOE:

Work Assignment Manager Name: Brian Schnitker (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0838 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Chemical and Hasard Exposure

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-06. Contractor shall provide work plan within 30 of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2019 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Jeffrey Taylor (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-8828
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

05/24/18

Statement of Work

Contract Number: EP-W-16-017
Work Assignment Number: 2-06

Title: Chemical Hazard and Exposure Evaluation and Risk Management

Purpose:

This work assignment continues and expands upon the work initiated under Work Assignment 1-06 of Contract EP-W-16-017. No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled *Chemical Hazard and Exposure Evaluation and Risk Management*, was developed to provide EPA with support in analyzing primarily existing chemicals and pursuing work for those chemicals that have the highest risk.

EPA's Existing Chemicals Program addresses pollution prevention, risk assessment, hazard and exposure assessment and characterization, and risk management for chemical substances in commercial use. For the chemicals that EPA identifies as high risk, EPA will choose from among many actions that it is authorized to take under the current Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Agency may pursue such regulatory actions as: restricting chemical use through banning its manufacture/import, issuing Significant New Use Rules that require manufacturers/importers to alert EPA of any new uses, and publishing test rules that require the chemical industry to supply EPA with additional data. Among other options, the Agency will also analyze safer substitute chemicals and consider voluntary phase-outs from the chemical manufacturers.

II. Scope of Work:

Task 1. Work Plan and Task Management

The contractor shall prepare and submit a technical and financial work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 5, 6, 7, and 8 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3. Rulemaking Support

The contractor shall help EPA develop rules, such as TSCA section 4 test rules that secure additional chemical data, section 5 Significant New Use Rules (SNURs) that affect new uses, and section 6 rules that restrict chemicals. Work may include analyzing literature sources or managing information that was developed by EPA or outside entities (e.g., other agencies, states, countries, NGOs, foundations, universities, and companies). The contractor may help collect, organize, and summarize public comments that are submitted by entities such as public interest groups, industry, academia, and others to EPA rulemaking dockets.

Task 4. Meeting & Workshop Support

The contractor shall assist EPA with meeting support by taking notes during meetings, such as at 1-to-2-hour meetings that involve a specific chemical or category of chemicals of concern, or at rulemaking consultation meetings that deal with tribal, small business, and state issues. The contractor will produce the meeting notes and also incorporate any edits to those notes provided by EPA. The contractor will support expert meeting workshops, such as regarding labeling for paint removal chemicals, and these workshops could require the contractor do many services, such as solicit attendees, organize logistics, facilitate the workshop, and summarize the discussions that take place at the workshop.

Task 5. Chemical Prioritization & Work Plan Chemicals

The contractor shall assist EPA with identifying priority chemicals for risk management analysis. Work could include securing lists of chemical that are being analyzed by: other countries, states within the United States, and EPA or other Federal agencies. The contractor may present information related to hazard, exposure, risk, and different environmental mediums such as air, water, and soil. The contractor may help EPA identify and take follow-up action on Work Plan chemicals that generally have the greatest risk concerns.

Task 6. Chemical Data Reporting (CDR)

The contractor shall assist EPA with managing chemical data under its CDR. Support can include working with the 2016 CDR and 2012 CDR data, helping with Internet and outreach materials, and producing statistics and chemical lists that relate to production volume, companies, industrial processing and use, and consumer and commercial use, among other information.

Task 7. High Production Volume (HPV) Chemical Management

The contractor shall continue to maintain HPV Challenge Program records, and conduct queries on HPV Challenge Program data if needed. The contractor may also perform work with other HPV chemicals.

Task 8. Miscellaneous Hazard, Exposure, and Risk Analyses

The contractor shall conduct analyses regarding other miscellaneous hazard, exposure, and risk management projects as the need arises.

III. Deliverables:

Task 1	The contractor shall prepare and submit the work plan in accordance with contract requirements.

Task 2	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3	Rulemaking Support	At WAM's Request.
Task 4	Meeting & Workshop Support	At WAM's Request.
Task 5	Chemical Prioritization & Work Plan Chemicals	At WAM's Request.
Task 6	Chemical Data Reporting (CDR)	At WAM's Request.
Task 7	HPV Chemical Management	At WAM's Request.
Task 8	Miscellaneous Hazard, Exposure, & Risk Analyses	At WAM's Request.

- **EPA will approve the work plan within 45 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **A work plan is required.**
- **CBI does apply.**
- **The work assignment relates to: Task II, Subtask 1; Task III, Subtasks 1, 8, and 13; and Task IV, Subtask 3 of the contract SOW.**

IV. Period of Performance:

This Work Assignment will begin on the date of the Contracting Officer's signature and extend through June 12, 2019.

V. Level of Effort:

The approximate level of effort described in this work assignment is 1,940 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative
Jeffrey Taylor
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Alternate Contracting Officer Representative
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Predictive Mathematical

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-07. Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Tony Mcdonald (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-1476
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

Battelle EPW16017 WA 2-07
Predictive Mathematical Modeling of Water Contaminant Mixture Data

Work Assignment 2-07

1) **Title:** Predictive Mathematical Modeling of Water Contaminant Mixture Data

Purpose

The Work Assignment is to provide statistical expertise and modeling in support of: a) research designed to understand the potential human health risk(s) associated with exposure to contaminants in water, such as disinfection byproducts (DBPs) and emerging contaminants including but not limited to algal toxins, transformation byproducts and anthropogenic chemicals; b) research designed to improve our ability to create appropriate groups of chemicals for experimental evaluation or risk assessment; and, c) research designed to improve our ability to predict accurately the joint toxic action of chemical mixtures and to determine those components responsible for the majority of the toxicity of the mixture. EPA is conducting this research program under the Safe and Sustainable Water Research (SSWR) National Research Program of the U.S. EPA. Specifically, this Work Assignment is for statistical effort to: review manuscripts intended for peer-reviewed journal publication for technical soundness and accuracy of described models and model outputs based on analyses conducted during the current work assignment period or previously by Battelle; extend the development and examination of approaches to discern the contributions of individual chemicals and chemical groups to the toxicity of a chemical mixture; conduct statistical analyses to examine the hypothesis that the toxicity of a group of chemicals can be predicted based on knowledge of the dose-response curves of the chemicals contained in the mixture; to develop, where needed, novel approaches, methods and analyses for grouping chemicals; to conduct research to enhance understanding of the joint toxic actions of groups of chemicals.; and, to provide expert consultation and advice in interpretation of results of analyses of chemical mixtures and groups.

Background

While the need for toxicological research with both defined and complex mixtures of DBPs and other chemical contaminants of water is well known, the lack of broadly-recognized appropriate statistical methods both to design appropriate experiments and the lack of accepted methods to determine when the effect of defined mixtures of chemicals deviates from that expected under an assumption of dose additivity, has hindered the ability to develop data needed by EPA to evaluate the potential human health risk that might be associated with exposure to the low levels of chemicals detected in water and those chemicals formed or transformed during disinfection of water (DBPs, transformation DBPs).

Under the Safe and Sustainable Water National Research Program (SSWR), EPA is conducting a series of studies to understand the toxicity of groups of water contaminants, including DBPs and transformation DBPs. DBPs and transformation DBPs are chemicals formed or transformed

during the disinfection of drinking water. DBPs have been associated with adverse health effects through epidemiological and toxicologic studies. In addition to DBPs, candidate contaminant list (CCL) chemicals and chemicals of emerging concern (CECs) are of interest, both individually and as groups. Studies at EPA are addressing different source waters and source water characteristics, different drinking waters (CCL and DBP focus) and wastewater treatments (CCL and DBP focus), with regard to the contaminants present and their concentrations, DBPs formed and their concentrations, and the relative toxic potency of the mixtures. Understanding those contaminants and contaminant groups that pose the greatest risks to human health will allow risk management and remediation efforts to focus on those that provide the greatest reduction in risk. Integrating toxicological assessments into risk remediation and reduction research provides the opportunity for remediation efforts to focus on those treatments/remedial activities that are most effective at reducing risk.

Predictive models for estimating the effects of contaminants groups will be used or developed/ revised where necessary and then used that have the ability to forecast the effects of contaminant groups from single chemical data, creating models that are predictive even when mixture composition changes (fewer chemicals in the mixture, more chemicals in the mixture, the mixing ratio changes as the mixture moves downstream or through the water system). Goals of this program include: development of flexible and accurate predictive models for estimation for toxicity of contaminant groups that allow for addition and deletion of contaminants and varied specification of chemical concentrations (to enhance usefulness across a spectrum of situations); an improved ability to determine those components responsible for the majority of the toxicity of the mixture; improved understanding of the potential human health risk(s) associated with exposure to environmentally realistic mixtures of contaminants in water; and, the ability to create appropriate groups of chemicals for experimental evaluation or risk assessment.

QA/QC elements consistent with the work requested will be observed during the conduct of this work assignment. These include: 1) before conducting analyses the contractor shall provide the EPA with summary statistics of the data that are being planned for analysis, consisting of sample means, sample standard deviations and sample size for each dose group; 2) potential data quality issues be presented as they are identified to EPA prior to proceeding further with analysis; 3) Resolution of data quality issues will be documented and approved by EPA before proceeding with analyses. The final report shall include a detailed description of all methods used; the results of analyses conducted, including confidence intervals, statistical significance, multiple comparisons (as appropriate); for any data analyses conducted, summary statistics of the data generated from the final program used to analyze the data shall be provided with the summary statistics consisting of sample means, sample standard deviations and sample size for each dose group and the programs used for analysis.

Scope of Work

The EPA Contracting Officer Representative will identify the specific deliverables, corresponding delivery dates, and provide additional technical clarification/directives regarding the tasks of the work assignment listed below through written technical directives (except for tasks 1, 2, and 3). Each initial deliverable shall be provided to the EPA Contracting Officer Representative in draft form for review and comment. The contractor shall incorporate procedures to ensure that these drafts completely document the methodologies; use appropriate assumptions; are accurate, complete, and as specified in the work assignment or written technical direction before providing them to the EPA. The contractor shall incorporate EPA review comments into revisions of the drafts. All drafts and final reports shall be approved by the EPA Contracting Officer Representative. A work plan is required (Task 1). CBI does not apply to this Contracting Officer Representative. This work assignment relates to the current Statement of Work (SOW) of the contract.

2) Tasks

Task 1. Workplan and Monthly Progress Report

(A) The Contractor shall prepare a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and, proposed staff names, hours and project roles.
(B) The Contractor shall provide a Table in the Monthly Progress Report that includes a cost summary that includes the hours allocated, the hours used this month and the cumulative hours used. The table shall also include the EPA technical contact, the contractor lead staff, the work assignment number and title and the date.

Task 2. Review Background Documentation

The contractor shall review relevant background documentation for each task. The EPA will provide publications and draft manuscripts to the contractor. Additionally, the EPA will serve as a resource for relevant literature and background materials relevant to completion of the tasks.

Task 3. Attend Teleconferences

The contractor shall participate in teleconferences to address any questions that the contractor may have regarding the scope and goals of tasks 5, 6, and 7 and discuss the data, analytic requirements, relevant background information and available literature. A kick-off teleconference shall be conducted specific to each of tasks 5, 6, and 7. Additionally, the EPA and the contractor shall have conference calls as needed to discuss and clarify technical issues related to the performance of each task. The contractor shall prepare summary notes which clearly summarize the teleconferences within five business days of each call.

Battelle EPW16017 WA 2-07
Predictive Mathematical Modeling of Water Contaminant Mixture Data

Task 4. Assess Data Quality

The contractor shall assess databases to evaluate their data quality and integrity. The contractor shall identify outliers and questionable data by reviewing data listings and summaries, applying statistical methods, and using graphical methods. The contractor also shall review the data for missing values, censoring patterns, and appropriate units of measure (e.g., milligrams/liter). Prior to use of the data, the contractor shall supply the EPA with summary data for each dose group proposed for inclusion in the analysis, including the dose level, n, mean and standard deviation and identify the specific source of the data.

Task 5. Review of Manuscripts

The contractor shall provide expert review of manuscripts prepared by the EPA for peer-reviewed publication, focusing on statistical methods, analyses of data and interpretation of such analyses, including figures, tables and text for statistical research conducted under EP-C-05-030, EP-W-09-024 and EP-W-16-017 (the current contract).

Task 6. Statistical Consideration of Stability of Chemical Composition of Complex Mixtures of Water Contaminants Across Mixtures and Over Time

The contractor shall conduct statistical research on chemical data collected by quantitative and qualitative analytic methods and determine whether the chemical composition (both for individual chemicals and combinations of chemicals) differs significantly across mixtures of DBPs that have been generated from the same or different source waters and/or different sources of natural organic matter and by different disinfection methods. The stability of the individual components and combinations of the mixtures over time shall be examined for time course data. Similar to research conducted under EP-C-05-030 and EP-W-16-017, the statistical weight of each DBP in a given DBP group (the linear combination weight percent, p_i) is proportional to its unitless concentration (w_i), which is calculated as follows: for each individual chemical, the overall mean concentration (g/L) is computed using all concentration measurements included in the analysis; the overall mean concentration (g/L) is divided by the chemical's molecular weight (g/mole) to convert means to molar concentrations (moles/L); and, the number of halogens in an individual chemical is multiplied by the chemical's molar concentration (moles/L) to compute the molar halogen concentration ($moles_H$/L). After examination of the data, the contractor shall propose a statistical analysis plan to the EPA Contracting Officer Representative. After review and approval by EPA, the contractor shall carry out the analysis plan.

Task 7. Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture

Using data and reports furnished by the U.S. EPA, the contractor shall provide expert

consultation with regard to mixtures analyses and, as directed, conduct statistical analyses to evaluate consistency with dose addition and estimate the contribution(s) of individual chemicals and chemical groups to the toxicity of a chemical mixture. The contractor shall also provide expert consultation that provides insights into the interpretation of the results of statistical analyses of mixtures data. The first effort consists of toxicity data on up to 9 haloacetic acids and haloacetic acid mixtures consisting of a varied number of chemicals, developed in *in vitro* and *ex vivo* assays. In addition to completion of analyses under EP-W-09-024 and WA-1 of the current contract, where data analyses focused on the dose addition and expected component contribution score methodology described in Hertzberg et al 2013 (*Toxicology*, 2013, 313:134-144), the contractor shall determine, whether predictions of mixture effect, made under dose addition assumptions and models or predictions of mixture toxicity made under independent action assumptions or models or predictions of mixture toxicity made using integrated addition methods (see for example Rider et al, 2008, *Int J Androl.* 31(2):249-62) more closely approximate the observed mixture response. The contractor shall also consider an analysis methodology similar to that described in detail by Altenburger et al., 2000 (*Environ Toxicology Chemistry*, 19(9): 2341–2347) where the 'best fitting model' of each chemical and mixture is used in the analysis.

For this first effort, the assay is a whole embryo culture assay. There are 6 endpoints of interest from the whole embryo cell culture assay: normal; dysmorphic, cranial NT, arch 1, heart, final somites. Three mixtures were tested. The three mixtures are related in that each is a mixture of up to nine haloacetic acids (HAAs). The nine haloacetic acids are: chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, dibromoacetic acid, tribromoacetic acid, bromochloroacetic acid, bromodichloroacetic acid and dibromochloroacetic acid. There are concentration response curves for each of these individual haloacetic acids.

Mixture LBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in low bromide source water disinfected by chlorination. The LBM mixture contains only 7 of the 9 HAAs, as two of them were not detected under low bromide conditions (the 2 that are absent are bromoacetic acid and dibromoacetic acid). Mixture MBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in medium bromide source water disinfected by chlorination. The MBM mixture contains all 9 of the HAAs. Mixture HBM is the mixture of these nine haloacetic acids representative of the mixing ratio (the relative proportions) of the 9 that are present in high bromide source water disinfected by chlorination. The HBM mixture contains 8 of the 9 HAAs as one of them was not detected under high bromide conditions (the one that was not detected was chloroacetic acid). The mixing ratios of the three mixtures (LBM, MBM and HBM) are different, so each one is a unique ray, both in the number of HAAs contained in the mixture (7,8,9 for LBM, MBM and HBM, respectively) and in the proportions of the HAAs relative to one another. There are concentration response curves for each of the three mixture rays (LBM, MBM, HBM).

Additional efforts will occur via amendments to the Work Assignment and will involve data sets transmitted by the U.S. EPA and discussed in detail with the contractor

Task 8. Develop computer programs

The contractor shall ensure that all databases, computer programs, and the corresponding documentation developed under this contract are accessible to the EPA Contracting Officer Representative, and persons authorized by them. The contractor shall provide this computer programming support to technically support the statistical analysis specified in other areas of this statement of work. All computer programs shall be well documented internally to facilitate EPA's review. Furthermore, the contractor shall use SAS for statistical analysis.

Task 9. Internal Documentation

The contractor shall internally document all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code so that results can be replicated even if the originating staff members are no longer available. The contractor shall provide access to this internal documentation upon request by the EPA Contracting Officer Representative. This documentation shall provide the foundation of the documentation of the products to be produced in the other areas of this Work Assignment (see #10)

Task 10. Prepare documentation

The contractor shall provide documentation for products in the other areas of this Work Assignment. The contractor shall provide documentation in computer files, and in hardcopy, upon specific request. The contractor shall incorporate EPA comments into revisions of the draft documentation. In all cases, the statistical algorithms and data used to generate results shall be provided electronically as well as in the appendix of the draft and final reports. The documentation shall include all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code used in accomplishment of the work effort.

In any documentation, the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support the results and any recommendations. The contractor also shall document alternative methods, procedures, and assumptions that the contractor considered in the statistical analysis. Further, the documentation shall be labeled with the name of the contractor, the EPA contract number (EPW16017) and the work assignment number (2-07).

3) Level of Effort

The approximate level of effort is 350 professional hours. Clerical hours are not included

4) Contracting Officer Representative

Tony McDonald
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Integrated Systems Toxicology Division
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e-mail: McDonald.Tony@epa.gov

5) Deliverables and Schedule

The following is a list of the deliverables required under this Work Assignment.

Task	Deliverable	Date
1	Initial Work plan	Due 15 days following receipt of Work Assignment (WA)
2	Review Background Documentation	Start upon receipt of the WA
3	Kick-Off Teleconferences for Tasks 5, 6 and 7	At the beginning of work on each task at a time mutually agreement to EPA and the contractor. First Teleconference to take place within 4 weeks of receipt of the WA
4	Assess Data Quality.	Following technical direction from the WA, assess data quality and prepare data quality reports. Revisions delivered as specified in technical directions.

Battelle EPW16017 WA 2-07
Predictive Mathematical Modeling of Water Contaminant Mixture Data

Task	Deliverable	Date
5	Review of Manuscripts	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*
6	Statistical Consideration of Stability of Chemical Composition of Complex Mixtures of Water Contaminants Across Mixtures and Over Time	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 30 days after request delivered and subsequent kick-off teleconferences*
7	Determine Consistency with Dose Addition and Estimate the Contribution(s) of Individual Chemicals and Chemical Groups to the Toxicity of a Chemical Mixture	Revisions delivered as specified in technical directions. Periodic Consultation, with Draft Reports due 45 days after request delivered and subsequent kick-off teleconferences*
8, 9, 10	Develop Computer Programs, Internal Documentation and Prepare Documentation	Perform and deliver for each of tasks 5, 6 and 7

* These dates may be modified by technical direction, rather than requiring workplan modification.

6) OTHER REQUIREMENTS

The contractor shall provide written notification to the Contracting Officer Representative when 75 percent of the hours and/or funds have been spent on this work assignment.

The contractor also shall immediately contact the EPA Contracting Officer Representative to discuss any problems that may adversely affect the work on this work assignment.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	RRP Outreach to Contractors

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-08. Contractors shall provide work plan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2019 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Darlene Leonard (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0516
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 2-08
Change Number: 0

Title: RRP Lead Outreach to Contractors

I. Purpose and Background

This project is a continuation of WA 1-08 on Contract Number EP-W-16-017. This Work Assignment continues and expands upon the work initiated in WA 0-08 under Contract EP-W-16-017 and provides technical support for the implementation of the Renovation, Repair and Painting Program. No work shall be repeated that was previously completed in WA 1-08.

Section 402(c) of TSCA authorizes EPA to promulgate regulations governing renovation activities conducted in homes built before 1978 that produce a lead-based paint hazard. EPA promulgated these regulations at 40 CFR part 745, Subpart E.

Under TSCA Section 404, EPA may authorize any State to administer and enforce the standards, regulations, or other requirements established under TSCA Sections 402 if the State has a program that is at least as protective of human health and the environment as the program specified in TSCA and that provides adequate enforcement. EPA's implementing regulations can be found at 40 CFR part 745, Subpart Q.

Section 404(h) of TSCA requires EPA to implement and enforce a federal lead based paint program in all States and Tribal areas that do not have an authorized program. EPA is permitted to use State and Tribal Assistance Grant funds to support implement the programs. (See 40 CFR 35.116, and 40 CFR 35.516.) Under this work assignment, EPA is seeking to increase the number of renovation contractors with RRP firm certification and/or those that take RRP training from an EPA authorized training provider.

II. Scope of Work

The Contractor shall:

- Continue to develop a program to encourage non-certified RRP firms to become certified or to renew their RRP firm certification in El Paso, TX, Denver, CO, Oakland, CA, Memphis, TN, Kansas City, MO, and Baltimore. Effort may involve:
    - Finalizing graphic ads, post cards, flyers, fact sheets, web banners, mailings, etc. for non-certified RRP firms developed under WA 0-08 on Contract Number EP-W-16-017 for each of the 6 cities identified above.
    - Printing and placing ads for each of the 6 cities identified above in this WA.

- Identify, reserve space, and pay (if required) for a venue for at least one lead outreach informational session event for non-certified RRP contractors in each city identified in WA 0-08 on Contract Number EP-W-16-017 to include but not limited to radio and TV interviews, town hall and local meetings or events. The Contractor shall work with the EPA Contracting Officer Representative (COR) to determine what the event will be held in each city. This effort will be done in coordination with WA 1-02 on Contract Number EP-W-16-017 in the same cities.

III. Deliverables:
Summary of Work – The Contractor shall submit to the EPA COR a report providing statistics on the activity for the contract period. The letter shall summarize the work completed and shall include what outreach activities occurred and the number of people reached. In addition, the report will include:

- A description of ads printed for each outreach session in each of the cities.
- A description of the actual outreach event held in each of the cities, including the name, location of the venue, date, and time.
- A description of the number of firms contacted and sources used to develop list of renovation firms to contact.
- An analysis of which outreach messages and delivery mechanism were most and least effective.

A work plan is required.
A Quality Assurance Project Plan is not required since no data collection is required.
CBI does not apply.

This work assignment relates to Tasks III and IV of the current Statement of Work (SOW) of the contract.

IV. Period of Performance:
This work assignment will start on June 13, 2018 and extend through June 12, 2019.

V. Level of Effort
The approximate LOE is 185 professional estimated hours.

VI. EPA Contacts:
Contracting Officer Representative:
Darlene Leonard
US EPA National Program Chemicals Division
Program Assessment and Outreach Branch (7404T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460 Phone: 202-566-1859

Deputy Contracting Officer Representative:
Julie Shannon
US EPA National Program Chemicals Division
Program Assessment and Outreach Branch (7404T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460 Phone: 202-564-8834

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-10

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021	New Chemical Program Support
	Base Option Period Number 2	

Contractor: Battelle Memorial Institute

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiating work assignment for the new period of performance than began on June 13, 2018. The contractor shall submit a workplan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2021 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Monica Miller (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

Battelle

Contract Number: EP-W-16017

Work Assignment Number: 2-10

Title: New Chemical Program Support

Purpose:

This work assignment will provide support the New Chemical Program (NCP) in processing of Pre Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment.

I. Background:

This work assignment, entitled *New Chemicals Program Support,* is to provide EPA with support to expedite the processing of the Pre-Manufacturer Notices (PMNs) to reduce the backlog and provide support brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will be an ongoing effort to: Provide PMN Status Tracking, Draft Letters and Consent Orders, Draft Significant New Use Rules (SNURs), Populate the Pre- Notice Communications Database, Provide Administrative Support to the New Chemicals Ad HOC Committee, and Provide Miscellaneous Administrative Support as the New Chemicals Program continues to develop as a result of the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing, processing and or use can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards, exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or

Significant New Use Rule (SNUR) which requires manufacturers/importers to alert EPA of any new uses of the new chemical substance.

II. Scope of Work:

The Contractor Shall:

Task 1. Work Plan and Monthly Progress Report

(A) Submit a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

(B) Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Used this month	Cum used

Through technical direction, the WAM will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

(C) Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA Project Officer. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's *TSCA CBI Protection Manual.*

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The

contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP.

Task 3. Document/Data Entry

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

Task 4. Document Sanitization

Sanitize documents by removing Confidential Business Information CBI from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Task 5. Tracking Support

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD.
PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Task 6. Consent Order and SNUR Development

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.
After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

Task 7. Pre-Notice Communication Program (New Task)

Provide support in Scanning Historical files containing information and notes on approximately 4000 Pre-Notice Communications including correspondence and meetings. The files will be used to modify and populate an existing database with existing and new metadata requested by the WAM.

Task 8. New Chemicals Ad Hoc Committee Support (New Task)

Provide support to the Ad Hoc committee on New Chemicals by drafting decision documents using a template and populating with data and information from Chemical Control Division briefing papers and Risk Assessment Division documents supporting review of New Chemicals. Attend Ad Hoc New Chemicals Prep meetings currently being held twice weekly and tracking progress of PMNs thru the Committee process.

Task 9. Miscellaneous Administrative Support (New Task)

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and files, tracking progress of work effort, database creation, population and maintenance and completing information requests.

III. Deliverables:

Task 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Task 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3.	Document/Data Entry	At WAM's Request.
Task 4.	Document Sanitization	At WAM's Request.
Task 5.	Tracking Support	At WAM's Request.
Task 6.	Consent Order and SNUR Development	At WAM's Request.
Task 7.	Pre- Notice Communication	At WAM's Request.
Task 8.	Ad Hoc Committee Support	At WAM's Request.
Task 9.	Miscellaneous Administrative Support	At WAM's Request.

- **EPA will approve the work plan within 30 days.**
- **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No

work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.

- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences**.

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2019.

V. Level of Effort:

The approximate level of effort for this work assignment is 3,110 professional hours.

VI. EPA Contacts:

Work Assignment Manager

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Alternate Work Assignment Manager

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-10

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2021 Base Option Period Number 2	New Chemical Program Support

Contractor: Battelle Memorial Institute

Specify Section and paragraph of Contract SOW: Contract SOW Delineation of Tasks - Task III

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Changes are highlighted in yellow. This amendment it to add a new Task- Task 10 - Determination Support - To provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. The level of effort for this new task is 610 hours.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 06/13/2016 To 06/12/2021		0
This Action:		0
Total:		0

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Monica Miller (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-6473 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

Contract Number: EP-W-16-017

Work Assignment Number: 2-10 Amendment to Add Task 10

Title: New Chemical Program Support

Purpose:

This work shall be performed under Battelle Contract EP-W-16-017, Task III Technical Program Support-General Support. This work assignment provides support to the New Chemical Program (NCP) in processing of Pre- Manufacturer Notices (PMNs). No work performed under previous work assignments will be duplicated under this work assignment. A new task is needed under this work assignment. The purpose of this new task, Task 10 - Determination Support, is to provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. This support will include sanitization of the determination and related support documents by removing Confidential Business Information (CBI); preparation of documents such as preambles and the statement of finding developed from boiler plates following instructions and using the information in the determination and support documents.

I. Background:

This work assignment, entitled *New Chemicals Program Support,* is to provide EPA with support to expedite the processing of the Pre-Manufacturer Notices (PMNs) to reduce the backlog and provide support brought about by the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This law became effective immediately upon being signed on June 22, 2016. The activities listed below will be an ongoing effort to: Provide PMN Status Tracking, Draft Letters and Consent Orders, Draft documentation needed for Significant New Use Rules (SNURs) and Statement on Administrator Finding to be published in the Federal register. Populate the Pre- Notice Communications Database, Provide Administrative Support to the New Chemicals Ad HOC Committee, and Provide Miscellaneous Administrative Support to the New Chemicals Program the program changes to implement the new law.

EPA's New Chemicals Program is required to review and make an affirmative determination of risk on new chemical substances submitted for evaluation in premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing, processing and or use can commence. The review evaluates a new chemical substance given the information provided by the submitter of the PMN and the information readily available to EPA to determine if the new chemical substance poses a risk to human

health or the environment. This review includes an evaluation of physical and chemical characteristics of the substance, the fate, the human health and environmental hazards, exposures, and risk management to make the affirmative determination of risk. Once the determination is made EPA may regulate the manufacturing, processing and or use of a new chemical substance through a Consent Order and/or Significant New Use Rule (SNUR) which requires manufacturers/importers to alert EPA of any new uses of the new chemical substance. If the determination of not likely to present an unreasonable risk to human health or the environment is made, a notice of the determination must also be published in the Federal Register.

II. Scope of Work:

The Contractor Shall:

Task 1. Work Plan and Monthly Progress Report

(A) Submit a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

(B) Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Used this month	Cum used

Through technical direction, the WAM will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

(C) Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA Project Officer. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's *TSCA CBI Protection Manual*.

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP.

Task 3. Document/Data Entry

Complete scanning and entering into PMN Gold all Consent Orders (sanitized and CBI), all CCD Briefing Papers and other CCD-generated documents. All documents scanned into PMN Gold soon will be migrated into phase 1 Enterprise Management System (EMS) by the Information Management Division (IMD).

Task 4. Document Sanitization

Sanitize documents by removing Confidential Business Information (CBI) from Risk Assessment Division (RAD) Section 5 Risk Assessment documents. This will increasingly be asked for by companies as EPA eliminates the practice of sending Action Letters immediately drafting Consent Orders to be sent to PMN submitters upon finalization of the affirmative risk finding and development of risk management options.

Task 5. Tracking Support

Complete simple spreadsheet created by NCP to track progress of eliminating the back log of cases as well as tracking the completion of information requests sent by PMs to be completed by RAD.
PMs will provide the status/ milestones to be tracked and added to the spreadsheet.

Task 6. Consent Order and SNUR Development

Provide support in developing draft TSCA section 5(e) Consent Orders and SNURs.
After collecting documentation from the Program Manager (PM) to include briefing papers, draft action letters, and other correspondence as well as data and information in PMN Gold and submitted PMNs, draft Consent Orders and SNURS. Drafts will be developed from boiler plates following instructions and using the information collected. After Draft is completed review with PM and prepare printed document for review and signature.

Task 7. Pre-Notice Communication Program (New Task)

Provide support in Scanning Historical files containing information and notes on approximately 4000 Pre-Notice Communications including correspondence and meetings. The files will be used to modify and populate an existing database with existing and new metadata requested by the WAM.

Task 8. New Chemicals Ad Hoc Committee Support (New Task)

Provide support to the Ad Hoc committee on New Chemicals by drafting decision documents using a template and populating with data and information from Chemical Control Division briefing papers and Risk Assessment Division documents supporting review of New Chemicals. Attend Ad Hoc New Chemicals Prep meetings currently being held twice weekly and tracking progress of PMNs thru the Committee process.

Task 9. Miscellaneous Administrative Support

Provide miscellaneous support to the New Chemicals Program as needed, which may include preparation, scanning, shredding, uploading etc. of documents and files, tracking progress of work effort, database creation, population and maintenance and completing information requests.

Task 10. Determination Support

Provide support, to make available to the public, all underlying documents supporting EPA's risk determinations. This support will include sanitization of the determination and related support documents by removing Confidential Business Information (CBI); preparation of documents such as preambles and the statement of finding developed from boiler plates, following instructions and using the information in the determination and support documents.

III. Deliverables:

Task 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Task 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3.	Document/Data Entry	At WAM's Request.
Task 4.	Document Sanitization	At WAM's Request.
Task 5.	Tracking Support	At WAM's Request.
Task 6.	Consent Order and SNUR Development	At WAM's Request.

Task 7.	Pre- Notice Communication	At WAM's Request.
Task 8.	Ad Hoc Committee Support	At WAM's Request.
Task 9.	Miscellaneous Administrative Support	At WAM's Request.
Task 10.	Determination Support	At WAM's Request.

- **A Quality Assurance Project Plan (QAPP) is necessary.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
- **CBI does apply.**
- **Contractor personnel shall at all times identify themselves as contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences**.

IV. Period of Performance:

This Work Assignment will start with the date of the Contracting Officer's signature and extend through - June 12, 2019.

V. Level of Effort:

The approximate level of effort for this new Task 10 is 610 hours.

VI. EPA Contacts:

Work Assignment Manager

Monica Miller
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Alternate Work Assignment Manager

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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-10

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2018 To 06/12/2019 Base X Option Period Number	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2018 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Rebecca Cool (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9138 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-4353 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019	New Chemical Program Support
	Base Option Period Number 2	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiating Work Assignment 2-11. Contractor shall provide a work within 30 days of reception.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Tracey Klosterman (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-2209 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

STATEMENT OF WORK

Contract Number: EP-W-16-017

Work Assignment: 2-11

Work Assignment (WA) Title: New Chemical Program Support for Significant New Use Rules, Consent Orders, and other New Chemical Regulatory Activities

Contract Officer Representative (COR)
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Alternate Contract Officer Representative (COR)
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BACKGROUND

The Premanufacture Notice (PMN) program is mandated by Section 5 of the Toxic Substances Control Act (TSCA). The law, enacted in 1976, gives the Environmental Protection Agency (EPA) broad authority to identify and control substances that pose a threat to human health or the environment. Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. EPA's New Chemicals Program (NCP), which is part of the Office of Pollution Prevention and Toxics (OPPT), is responsible for coordinating the review process of PMN submissions and identifying new substances that require regulatory action. The New Chemicals Management Branch (NCMB) in the Chemical Control Division (CCD) of OPPT is responsible for the risk management of new chemicals.

During the Agency's review period, EPA must determine whether the chemical should be regulated because it has insufficient information to make a determination; may present an unreasonable risk; or presents an unreasonable risk to human health or the environment. One method of regulation is for the EPA to enter into a TSCA Section 5 Order with the Company which allows production of the chemical to proceed under specific restrictions. Under the Expedited Follow-up Rule effective October 10, 1989, when a Section 5 Order is issued for a new chemical substance, EPA is obligated to issue a Significant New Use Rule (SNUR) within a limited period of time. Other deadlines exist for previously issued 5(e) Orders and for new chemical substances that pass through new chemical review but are identified as 5(a)(2) SNUR candidates. The purpose of the Significant New Use Rule (SNUR) is to extend regulation of new chemicals beyond the PMN submitter.

In an effort to make TSCA regulatory actions more readily available to other government agencies, as well as the public, CCD will utilize information contained in the CCD Notice Tracking database to create an MS Access Database to populate the ChemView system for generation of Chemview Templates. All information uploaded into the ChemView system would not contain Confidential Business Information (CBI).

The purpose of this work assignment is to provide technical support to EPA for TSCA Section 5 Actions in the areas of: (1) collection, review, and formatting of supporting and documents, (2) coordination of chemical identity verification, (3) data entry of information into the CCD Notice Tracking database, and (4) provide technical assistance to EPA CORs in uploading the resulting MS Access Database files into ChemView. This work assignment will involve the use of TSCA Confidential Business Information.

PERIOD OF PERFORMANCE: Date of issuance through June 12, 2019.

LEVEL OF EFFORT (LOE): The approximate LOE for this Work Assignment is 3,000 hours.

Task 1: Work Plan and Task Management

The contractor shall: Prepare and submit a work plan in accordance with the requirements of this contract. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management.

Task 2: Quality Assurance Project Plan (QAPP)

The contractor shall: Create a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5) that documents the planning, implementation, and assessment procedures in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/quality and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Task 3: Collection of Supporting Documents

The contactor shall: Initiate collection of supporting and source documents including PMN submissions, EPA review reports, Federal Register Notices, TSCA Section 5 Orders, and Not Likely Determinations for PMNs identified by the COR in written technical direction. The Contractor shall utilize all available resources, including the CIS and NCR databases - electronic version of the files from the Confidential Business Information Center (CBIC), PMN Gold Workflow System, the CBI LAN, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI, however, they are located in a CBI environment. In those instances, when the documents are not

located in a CBI environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall: Create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Contract Officer Representative (COR) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Contract Officer Representative (COR) of any files which are missing.

Task 4: Formatting of Supporting Documents

The contractor shall: Provide technical assistance to the COR in formatting of supporting documents as Adobe pdfs. The COR shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the ChemView system. Formatted pdf documents must be text searchable to accommodate the functionality within the ChemView system.

The contractor shall: Track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For the signed TSCA Section 5 Orders, the contractor shall notify the COR of any delays in completion of the reports, and to obtain any sanitized orders that are not available. As the EPA contact, the COR is responsible for certifying that all formatted documents are suitable for transmission to the ChemView system.

Task 5: CCD Notice Tracking database

The contractor shall: Use the collected TSCA Section 5 information to review and populate tables within the CCD Notice Tracking database. All identified chemicals shall be entered into the system using the guidance documents provided by the COR. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the COR. Using the information contained in the database, the contractor shall create MS Access database files for upload into the Chemview system. The Chemview workgroup will review all data and uploaded support documents prior to final approval and publication in the public Chemview database.

5.1 Chemical Identity Verification

The contractor shall: Review and capture information from the sanitized documents to populate the chemical identities included in the TSCA Section 5 Submissions, Orders, SNURs or Not Likely Determination. This identity will include the Non-Confidential name, as well as any public CAS/Accession Number where available. The COR shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide

what information is available, and the EPA COR will coordinate verification of the suitable names.

The contractor shall: Use the biannually updated TSCA Inventory to update chemical identities for Section 5 data in ChemView and collect and record chemical identity information for TSCA Section 5 Actions reportable under TSCA Section 12(b).

5.2 Database Data Entry

The contractor shall: Use the non-confidential documents collected, and guidance provided by the COR to enter data into the CCD Notice Tracking database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. Any questions should be posed to the COR as soon as possible to allow additional guidance to be provided.

In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the COR to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the COR.

5.3 Report Generation

The contractor shall: Assist the EPA COR in creation of various reports using the export functions of the CCD Notice Tracking database. The contractor shall coordinate with the COR the procedures for generation of the reports and any formatting requirements that may be needed.

Task 6: QA/QC of ChemView System Content

The contractor shall: Assist the EPA COR in review of the current ChemView content in comparison to the New Chemicals Status and Determinations Tables, as well as verification of the accuracy of all data and links contained within each EPA Action output. The contractor shall report weekly on any findings, and deliver all requisite information necessary for addressing the error.

DELIVERABLES: All deliverables shall be submitted to the COR electronically (Adobe pdf).

Task 1.	The contractor shall: Prepare and submit the work plan in accordance with contract requirements.	
Task 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	 • 10 days after WA begins • Prior to work on environmental data activities
Task 3.	Collection of Supporting Documents (Status Update to include including identification of missing documents.)	At COR's Request.
Task 4.	Formatting of Supporting Documents (Monthly status update to include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for COR review.)	At COR's Request.
Task 5.	CCD Notice Tracking database and monthly (Monthly status update to include the progress of chemical identity verification, including notation of changes in identities and any updates made to the CCD Notice Tracking database; progress on the completion of the data entry; and report generation.)	At COR's Request.
Task 6.	QA/QC of ChemView System Content (Monthly status update to include the progress of QA/QC of ChemView content, including notation of changes to support documents and any updates made to the CCD Notice Tracking database; progress on the continued review of content; and report generation.)	At COR's Request.

ADDITIONAL INFORMATION

- Contractor personnel shall: Identify themselves as contractor employees at all times, and shall not present themselves as EPA employees. Furthermore, they shall not represent

views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019	CBI LAN Reviews
	Base Option Period Number 2	

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-12. Contractor shall provide work plan within 30 days of receipt of the work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2019 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Skyler Dobert (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3159
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-9863
	FAX Number:	

Statement of Work

Contract Number: EP-W-16-017
Work Assignment Number: 2-12

Title: Support for CBI Reviews as Required by TSCA section 14(g)

Purpose:

The Purpose of this Work Assignment is to assemble and extract selected data from TSCA submissions containing information claimed as CBI, and provide a written analysis sufficient to allow for the program office consideration of the validity of the identified CBI claims and then the generation of a recommendation to meet the requirements for a final determination as required under TSCA section 14(g) data related to submitted with new chemical notices and input the information into appropriate databases. The level of detail will vary depending on the type of filing subject to review, and relevant statutory, regulatory and policy considerations.

I. Background:

The Office of Pollution Prevention and Toxics (OPPT) is charged under the Toxic Substances Control Act (TSCA) with reviewing confidential business information (CBI) claims and making recommendations for final determinations concerning the potential validity of these claims. TSCA section 14(g). Because of the statutory mandate that these reviews occur within ninety days of receipt of the documents, identification of the claims, initial data entry, data assembly/extraction, and creation of useful and related information products must occur in a timely fashion in order for it to be used in the statutorily mandated process. These documents will be TSCA submissions directed to the Agency under all provisions of TSCA, as well as follow-up materials, including amendments and substantiations or responses to requests for comments. To address this broad need, the EPA will rely on contractor support to assist in the extraction, summary, and initial analysis/assessment of the data to facilitate the Agency CBI review and determination process.

II. Scope of Work:

Subtask 1. Work Plan and Task Management

The Contractor shall submit a work plan that describes tasks, the planned approach, schedule, estimated direct labor hours by labor level, and associated budget. The Contractor may request a meeting (via conference call) with the Contracting Officer Representative to seek clarification or to answer any questions prior to the submission of the above work plan.

Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the WAM regarding the status of the work assignment. Additional points of contact under this work assignment are noted below in VI EPA contacts.

Subtask 2. Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) is required. A Quality Assurance Project Plan documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities. It integrates all the technical and quality aspects of the project in order to provide a "blueprint" for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an

approved Quality Assurance Project Plan. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the Contractor shall be responsible for the development and revisions to the QAPP.

Subtask 3. TSCA CBI reviews

The Contractor shall review all documents subject to the TSCA 14(g) CBI review requirements, and extract from each file the data and studies pertinent to the assessment of the CBI claims. These will largely be extracted from substantiations as authorized under the regulations and policies provided by the information submitters.

a. The Contractor shall cause the data to be abstracted and entered into the designated database or spread sheet or template.

b. The Contractor shall also summarize the basis for the submitters' claims of confidentiality, providing specific sources for the summary points (e.g. loss of competitive advantage, Response 3, secret that substance is in commerce, Response 6 etc.) The Contractor shall provide a written analysis sufficient to allow for the Program Office consideration of the validity of the identified CBI claims.

c. The Contractor shall be called to engage in literature searches related to the reviews.

d. The activities and the generated work-products of the Contractor shall be assembled into formats and template of the Program Office's design.

e. The Contractor shall participate in meetings and trainings related to TSCA CBI reviews and incorporate EPA procedural updates in to the workflow as appropriate.

Subtask 4. Confidentiality

The majority of the material related to this activity is claimed by the submitters as TSCA Confidential Business Information, TSCA CBI clearance and adherence to TSCA CBI procedures are required through the duration of the WA.

III. Deliverables:

Subtask 1.	The contractor shall prepare and submit the work plan in accordance with contract requirements. Upon approval of the work plan, the Contractor shall maintain at least biweekly communication with the WAM.	• At the start of the WA. • Bi-weekly status meetings with WAM.
Subtask 2.	Quality Assurance Project Plan (QAPP) • Initial QAPP • Revised QAPP(s)	• 10 days after WA begins • Prior to work on environmental data activities
Subtask 3.	TSCA CBI reviews	At WAM's Request.

Subtask 4.	The Contractor shall gain and maintain TSCA CBI clearance through the duration of the work assignment	At the start of the WA.

- **EPA will approve the work plan within 45 days.**

A Quality Assurance Project Plan (QAPP) is required. The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following OPPT/EPA guideline. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.

- **A work plan is required.**
- **CBI does apply.**

IV. Period of Performance: the WA will begin on the date of the Contracting Officers Signature and end on 6/12/2018

V. The approximate LOE is: 2206 professional hours.

VI. EPA Contacts:

Primary Contracting Officer Representative
Skyler Dobert
WJC East Building, Rm 4218-C, MC 7408M
1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-3159
Dobert.skyler@epa.gov

Alternate Contracting Officer Representative
Tyrone Thomas
OCSPP/OPPT/EAD
U.S. Environmental Protection Agency
Washington, DC 20460
(202) 564-3121

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Endocrine Disruptor Screening

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-13. Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharlene Matten (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-0130 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

Updated 6/4/2018

Contract Number: EP-W-16-017
Work Assignment Number 2-13

Title: Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support

Contracting Officer Representative
Sharlene Matten, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-0130
Email: matten.sharlene@epa.gov

Alternate Contracting Officer Representative
Scott Lynn, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8430
Email: lynn.scott@epa.gov

Alternate Contracting Officer Representative
Kristan Markey, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8716
Email: markey.kristan@epa.gov

Purpose:

This work assignment, *Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support,* shall provide support to the Endocrine Disruptor Screening Program (EDSP). No work performed under previous task orders or work assignments will be duplicated under Work Assignment 2-13, EP-W-16-017. Some of the work is a continuation of work initiated under Work Assignment 1-13, EP-W-16-017. The period of performance is June 13, 2018 to June 12, 2019.

I. Level of Effort

The approximate LOE for this work assignment is **2,065** hours.

II. Background

This work assignment, *Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support* will provide support to the Office of Science Coordination and Policy in five (5) general areas:

1. Records Management
2. Data Platforms for E-file Organization and Management
3. Data Analysis and Statistical Support
4. Meeting Management
5. Special Projects.

The Endocrine Disruptor Screening Program (EDSP) was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results, allowing for greater coverage of the endocrine system.

III. Tasks

For each Task below, the Contractor shall:

Task 1. Work Plan and Task Management

1. Submit a work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

3. Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

4. The contractor shall immediately notify the EPA COR if there are any problems that affect the production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA COR, Battelle shall provide a secure method for internet transfer of large files. All Deliverables for WA 1-13 are the property of EPA.

6. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

7. Some work may require access to FIFRA sensitive materials. The manager of this work assignment, as well as any staff working with FIFRA sensitive materials must be FIFRA CBI cleared. They must also take required FIFRA CBI training designated by the EPA COR as described in EPA's *FIFRA CBI Protection Manual.*

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP or a revised QAPP indicating where changes have been made. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. The contractor shall be responsible for the development of, and any revisions to, the QAPP.

Task 3. Records Management

The contract shall provide EPA with technical assistance on activities related to records management.

1. The contractor shall assist EPA in managing records, in all media, according to the disposition instructions in EPA record management schedules, including but not limited to:
    - EPA Record Schedule 1035 - Environmental Records
    - EPA Record Schedule 1004 - Acquisitions and Contracts
    - EPA Records Schedule 1024 - Federal Advisory Committee Records
2. The contractor shall provide support for:
    - Organizing and indexing records
    - Packing and labeling boxes containing records for transfer to a Federal Records Center (FRC) or as a direct offer to the National Archives and Records Administration (NARA)
    - Preparing individual box lists
    - Preparing destruction lists for records that will be destroyed and destroying them
    - E-record management
3. The contractor shall provide the COR with:
    - Draft and final indices of records (in all media)

- Draft and final box lists
- Organized, packed, and labelled records boxes for transfer to FRC or NARA
- Draft and final records destruction forms.

4. The contractor shall conduct work with paper records at EPA William Jefferson Clinton East, Office of Science and Coordination Policy, Washington D.C., unless otherwise dictated by the EPA COR.
5. The contractor shall have approximately one technical meeting per week with Battelle and/or its subcontractor.

Task 4. Data Platforms for E-file Organization and Management

The contractor shall assist in the follow activities:

1. Assess the EDSP e-file document management and storage systems and recommend options to meet programmatic and scientific needs.
2. Support the development of an EDSP taxonomy structure for e-file organization
3. Provide a cost analysis for implementation of options
4. Implement preferred option.

Task 5: Meeting Management

The contractor shall provide EPA with support for internal (EPA) (e.g., EPA workgroup meetings) and external (public) meetings (e.g., workshops)

Examples include:

1. Logistical support for planning meetings
2. Note-taking, transcription, recording, and reports from meetings.

Task 6: Data Analysis and Statistical Support

The contractor shall provide EPA with technical assistance in data and biostatistical analysis, particularly data from toxicological/toxicokinetic studies. EPA may order work that requires a short turn-around time. Battelle shall use, to the extent possible, open source tools, e.g., programs in R.

The contractor shall provide support for:

1. Data and statistical analysis, e.g., compiling and evaluating *in vitro* and *in vivo* data from multiple sources, preparing or revising reports, statistical support and data analysis for publication, preparing data evaluation records using EPA study profile templates for the EDSP, *etc.*;
2. Data management related to specific data/statistical analyses.

Examples include:

1. Development of EPA Data Evaluation Records from EPA-sponsored laboratory studies including supporting statistical analysis, as needed.
2. Statistical analysis of EPA data either for an individual study or multiple studies
3. Meta-analysis of collected data from EPA or published *in vitro*/*in vivo* studies
4. RSCABS of EPA histopathology data

5. Data and statistical analysis of EPA toxicokinetics data
6. Cross-species analyses
7. *In vitro* to *in vivo* extrapolation (dosimetry)
8. Analysis of *in vitro* toxicokinetics data in trout, rat, and human.

Task 7: Special Projects

The contractor shall provide EPA with technical assistance including, but not limited to, studies that measure, detect, or reduce exposure to toxic substances in the EDSP Universe and the TSCA work plan. Studies may include:

- testing physical-chemical properties,
- collecting *in vitro* toxicokinetic and biochemical data.

The test data will support parameterizing and increasing the predictivity of computational toxicology modeling (e.g., adverse outcome pathway outcomes, physiologically-based toxicokinetics, exposure (reverse toxicokinetics/dosimetry) assessment, endocrine bioactivity assessment), identifying data gaps, and modifying test procedures for high-throughput platforms. For example, EPA has designed a Cell Culture Exposure System for *in vitro* testing of volatile chemicals. This system needs further evaluation for use in a high throughput setting.

IV. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Task No.	Deliverable Title/Brief Description	Due Date
1	Technical and Financial Work Plan	
1	Monthly Technical and Financial Report	
1	Bi-monthly Status Meetings (telephone or internet, e.g., Skype)	
2	Draft QAPP	
2	Final QAPP	
3	Records Management	TBD in technical direction
4	Data Platforms for E-file Organization and Management	TBD in technical direction
5	Meeting Support	TBD in technical direction
6	Data Analysis and Statistical Support	TBD in technical direction
7	Special Projects	TBD in technical direction

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-13

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2018 To 06/12/2019 Base Option Period Number 2	Endocrine Disruptor Screening

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Battelle EPW16017 WA 2-13 The purpose of this work assignment amendment is to add 300 hours to the LOE to complete work under Task 6 and to adjust the LOE for Task 1. The addition will bring the total Work Assignment LOE to 2365. Add Scott Lynn as Alternate WACOR

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
This Action:	06/13/2018 To 06/12/2019		
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:		Cost/Fee	LOE:
Cumulative Approved:		Cost/Fee	LOE:

Work Assignment Manager Name: Sharlene Matten (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-0130
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-3121
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-564-4353
	FAX Number:	

Contract Number: EP-W-16-017
Work Assignment Number 2-13, Amended

Title: Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support

Contracting Officer Representative
Sharlene Matten, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-0130
Email: matten.sharlene@epa.gov

Request to ADD: Alternate Contracting Officer Representative
Scott Lynn, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8430
Email: lynn.scott@epa.gov

***Request to Remove*:** Alternate Contracting Officer Representative
Kristan Markey, Ph.D.
Exposure Assessment Coordination and Policy Division
Tel. (202) 564-8716
Email: markey.kristan@epa.gov

Purpose:

This work shall be performed under Battelle Contract EP-W-16-017, Task II Data Analysis and Task III Technical Program Support- General Support. This work assignment, *Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support,* shall provide statistical and technical support for the assessment of toxic substance under the Endocrine Disruptor Screening Program (EDSP). No work performed under previous work assignments will be duplicated under this work assignment. The purpose of this amended work assignment (WA 2-13) is to add 300 hours to the LOE to complete work under Task 6 and to adjust the LOE for Task 1. In addition, Task 7, Special Studies, is no longer needed. The period of performance is June 13, 2018 to June 12, 2019.

I. Level of Effort

The approximate LOE for this work assignment is **2,065** hours. **Request 300 hour increase in LOE.**

II. Background

This work assignment, *Office of Science Coordination and Policy, Endocrine Disruptor Screening Program Technical and Program Management Support* will provide support to the Office of Science Coordination and Policy in five (5) general areas:

1. Records Management
2. Data Platforms for E-file Organization and Management

3. Data Analysis and Statistical Support
4. Meeting Management
5. Special Projects.

The Endocrine Disruptor Screening Program (EDSP) was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two-tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results, allowing for greater coverage of the endocrine system.

III. Tasks

For each Task below, the Contractor shall:

Task 1. Work Plan and Task Management. Request to increase the LOE to manage the tasks in the work assignment.

1. Submit a revised work plan describing tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

3. Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

4. The contractor shall immediately notify the EPA COR if there are any problems that affect the production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA COR, Battelle shall provide a secure method for internet transfer of large files. All Deliverables for WA 1-13 are the property of EPA.

6. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

7. Some work may require access to FIFRA sensitive materials. The manager of this work assignment, as well as any staff working with FIFRA sensitive materials must be FIFRA CBI cleared. They must also take required FIFRA CBI training designated by the EPA COR as described in EPA's *FIFRA CBI Protection Manual.*

Task 2. Quality Assurance Project Plan (QAPP)

The contractor shall submit a Quality Assurance Project Plan (QAPP) in accordance with the Agency requirements for QAPP (QA/R-5). Detailed information may be found at www.epa.gov/quality. The contractor shall update the QAPP as needed (and in any case, at least once a year). For QAPP revisions, the contractor shall provide a list summarizing changes from the prior approved QAPP or a revised QAPP indicating where changes have been made. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. The contractor shall be responsible for the development of, and any revisions to, the QAPP.

Task 3. Records Management

The contract shall provide EPA with technical assistance on activities related to records management.

1. The contractor shall assist EPA in managing records, in all media, according to the disposition instructions in EPA record management schedules, including but not limited to:

- EPA Record Schedule 1035 - Environmental Records
- EPA Record Schedule 1004 - Acquisitions and Contracts
- EPA Records Schedule 1024 - Federal Advisory Committee Records

2. The contractor shall provide support for:
    - Organizing and indexing records
    - Packing and labeling boxes containing records for transfer to a Federal Records Center (FRC) or as a direct offer to the National Archives and Records Administration (NARA)
    - Preparing individual box lists
    - Preparing destruction lists for records that will be destroyed and destroying them
    - E-record management
3. The contractor shall provide the COR with:
    - Draft and final indices of records (in all media)
    - Draft and final box lists
    - Organized, packed, and labelled records boxes for transfer to FRC or NARA
    - Draft and final records destruction forms.
4. The contractor shall conduct work with paper records at EPA William Jefferson Clinton East, Office of Science and Coordination Policy, Washington D.C., unless otherwise dictated by the EPA COR.
5. The contractor shall have approximately one technical meeting per week with Battelle and/or its subcontractor.

Task 4. Data Platforms for E-file Organization and Management (WORK COMPLETED)

The contractor shall assist in the follow activities:

1. Assess the EDSP e-file document management and storage systems and recommend options to meet programmatic and scientific needs.
2. Support the development of an EDSP taxonomy structure for e-file organization
3. Provide a cost analysis for implementation of options
4. Implement preferred option.

Task 5: Meeting Management (WORK COMPLETED)

The contractor shall provide EPA with support for internal (EPA) (e.g., EPA workgroup meetings) and external (public) meetings (e.g., workshops)

Examples include:

1. Logistical support for planning meetings
2. Note-taking, transcription, recording, and reports from meetings.

Task 6: Data Analysis and Statistical Support. Request an increase in the LOE to complete work under Task 6.

The contractor shall provide EPA with technical assistance in data and biostatistical analysis, particularly data from toxicological/toxicokinetic studies. EPA may order work that requires a short turn-around time. Battelle shall use, to the extent possible, open source tools, e.g., programs in R.

The contractor shall provide support for:

1. Data and statistical analysis, e.g., compiling and evaluating *in vitro* and *in vivo* data from multiple sources, preparing or revising reports, statistical support and data analysis for publication, preparing data evaluation records using EPA study profile templates for the EDSP, *etc.*;
2. Data management related to specific data/statistical analyses.

Examples include:

1. Development of EPA Data Evaluation Records from EPA-sponsored laboratory studies including supporting statistical analysis, as needed.
2. Statistical analysis of EPA data either for an individual study or multiple studies
3. Meta-analysis of collected data from EPA or published *in vitro*/*in vivo* studies
4. RSCABS of EPA histopathology data
5. Data and statistical analysis of EPA toxicokinetics data
6. Cross-species analyses
7. *In vitro* to *in vivo* extrapolation (dosimetry)
8. Analysis of *in vitro* toxicokinetics data in trout, rat, and human.

~~**Task 7: Special Projects (DELETE)**~~

~~The contractor shall provide EPA with technical assistance including, but not limited to, studies that measure, detect, or reduce exposure to toxic substances in the EDSP Universe and the TSCA work plan. Studies may include:~~

- ~~testing physical-chemical properties,~~
- ~~collecting *in vitro* toxicokinetic and biochemical data.~~

~~The test data will support parameterizing and increasing the predictivity of computational toxicology modeling (e.g., adverse outcome pathway outcomes, physiologically-based toxicokinetics, exposure (reverse toxicokinetics/dosimetry) assessment, endocrine bioactivity assessment), identifying data gaps, and modifying test procedures for high-throughput platforms. For example, EPA has designed a Cell Culture Exposure System for *in vitro* testing of volatile chemicals. This system needs further evaluation for use in a high throughput setting.~~

IV. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule - All deliverables must be completed by June 12, 2019

Task No.	Deliverable Title/Brief Description	Due Date
1	Revised Technical and Financial Work Plan	15 calendar days after receipt of work assignment
1	Monthly Technical and Financial Report	15th of each month
1	Bi-monthly Status Meetings (telephone or internet, e.g., Skype)	Approximately every 2 weeks
2	Draft QAPP	
2	Final QAPP	
3	Records Management	TBD in technical direction
4	Data Platforms for E-file Organization and Management	TBD in technical direction
5	Meeting Support	TBD in technical direction
6	Data Analysis and Statistical Support	TBD in technical direction
~~7~~	~~Special Projects~~	~~TBD in technical direction~~

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Systematic Review Support

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-14. Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Kristan Markey (Signature) (Date)	Branch/Mail Code: Phone Number: 202 564 8716 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

Contract Number: EP-W-16-017
Work Assignment Number: 2-14

Title: EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support

Purpose:

This work assignment, *EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support*, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPAs Office of Chemical Safety & Pollution Prevention (OCSPP) including the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 2-14, EP-W-16-017. However, much of the work is a continuation of EP-W-16-017 Work Assignment 1-14.

I. Background

This work assignment will provide technical support in three specific areas:

1. Support the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act via development of an inventory of testing requests and existing data and analysis of this inventory;
2. Support EDSP linear and pathway-based systematic literature reviews to support the performance-based validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies
3. Support collecting, prioritizing, and analyzing in vitro and in vivo data for display on the EPA Comptox dashboard via systematic review (SR) and high-throughput assays (in vitro only)

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system.

I. Statement of Work

Subtask 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Hours used this month	Cumulative hours used

Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

3. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.

4. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.

6. All Deliverables for WA 2-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).

7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 4, and 5 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information

needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy

1. **Data Processing on Testing Requests and Requirements**. The contractor shall convert data from TSCA Section 4 & 5 regulatory letters and databases and TSCA Sections 4, 5, and 8 hazard and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.

2. **Data Processing on Existing Chemical Data**. The contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record.

3. **Data Analysis.** The contractor shall determine which tests are most commonly requested and determine trends of data requests based on chemical classes and other variables. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies.

Subtask 4. EDSP linear and pathway-based systematic literature reviews

1. **Continuation of EDSP Linear Systematic Literature Reviews**. The Contractor shall continue to support EPA with scientific expertise to perform title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on the Fish Short-Term Reproduction Assay (FSTRA), and Male and Female Pubertal Assays initiated under EPW-11-063, Task Order 11; and the Amphibian Metamorphosis Assay and cross-species Fish Short Term Reproduction Assay initiated under EPW-11-063, Task Order 16.

2. **EDSP pathway-based systematic literature reviews**. The Contractor shall assist EPA with developing and implementing approaches for pathway-based systematic literature reviews such as the steroidogenesis and thyroid-related pathways and molecular-initiating events (MIEs). Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design, workflow management, and support of automated approaches.

3. **Data management of EDSP Systematic Reviews.** The Contractor shall support the development and implementation EDSP and OECD Harmonized Templates, reviewer workflows, and reference management in systematic review tools selected by EPA.

4. **Analysis of EDSP Systematic Reviews**. The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), toxicological, and textual analysis (such as text mining and natural language processing analysis) of EDSP systematic reviews and other data streams.

Subtask 5: Development and Prioritization of the EDSP Universe 3.0

1. The Contractor shall support the curation, clustering, and prioritization of chemical substances from the EDSP Universe of Chemicals including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
2. Develop an experimental data extraction and curation approach and/or QSAR model(s) to represent and associate relevant physical-chemical test data for each substance in the EDSP Universe 3.0
3. Develop decision support framework and analysis to prioritize, deprioritize, exclude, and cluster substances for testing in EDSP relevant assays based on experimental or modelled physical-chemical properties or chemical structure.

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Tasks	Deliverables	Due Dates
Subtask 1	Work plan and task management The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2	Quality Assurance Project Plan (QAPP) 1. Draft QAPP 2. Final QAPP	1. Draft: 10 days after WA begins 2. Prior to work on environmental data activities
Subtask 3	Development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy	At Work Assignment COR's request.
Subtask 4	EDSP linear and pathway-based systematic literature reviews	At Work Assignment COR's request.
Subtask 5	Development and Prioritization of the EDSP Universe	At Work Assignment COR's request.

1. **EPA will approve the work plan within 30 days.**
2. **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
3. **This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2;** otherwise, no CBI is involved.
4. **Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently**

governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2019.

IV. Estimated Level of Effort: 1,250 professional hours.

V. EPA Contacts:

Primary Contracting Officer Representative
Kristan Markey
WJC East Building, Rm 4106-H, MC 7203
1200 Penn. Ave, NW, Washington, DC 20460
Phone: (202) 564-8716
markey.kristan@epa.gov

Alternate Contracting Officer Representative
Ronnie "Joe" Bever
WJC East Building, Rm 4106-J, MC 7203
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bever.ronnie@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2018 To 06/12/2019 Base Option Period Number 2	Alternative Testing Strategy,

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Battelle EPW16017 WA 2-14 The purpose of this amendment is to request 350 hours increase in LOE for Subtask 3 and 275 hours for Subtask 4. The total amendment requested LOE is 625. This request will bring the total number of hours for WA 2-14 to 1875.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	06/13/2018 To 06/12/2019		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Kristan Markey (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202 564 8716	
	FAX Number:	
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-564-3121	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Jody Gosnell (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-564-4353	
	FAX Number:	

Contract Number: EP-W-16-017

Work Assignment Number: 2-14, Amended 2019-04-08

Title: EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support

Contracting Officer Representative
Kristan Markey
Exposure Assessment Coordination and Policy Division
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Alternate Contracting Officer Representative
Ronnie "Joe" Bever
Exposure Assessment Coordination and Policy Division
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Purpose:

This work assignment, *EPA Office of Science and Coordination Policy, Alternative Testing Strategy, Data Science, and Systematic Review Support*, will provide technical support to the Office of Science Coordination and Policy (OSCP) in EPAs Office of Chemical Safety & Pollution Prevention (OCSPP) including the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy, performance-validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies; and development and prioritization of chemicals in EPA's Endocrine Disruptor Screening Program. No work performed under previous task orders or work assignments will be duplicated under Work Assignment 2-14, EP-W-16-017. However, much of the work is a continuation of EP-W-16-017 Work Assignment 1-14.

I. Level of Effort

The approximate LOE for this amended work assignment is 1,875 hours from 1,250 hours. This includes a request for 350 hours increase in LOE for Subtask 3 and 275 hours for Subtask 4. OSCP has already moved hours and dollars from task 5 to tasks 3 & 4. Battelle may expend a maximum of 81 hours on Subtask 4.4,

The amendment is necessary because specific projects envisaged under this WA 2-14 have taken additional resources to overcome hurdles identified along the way. This includes, for example, data clean-up necessary for affecting the Steroidogenesis Meta-Analysis Project (initiated by technical directive under WA 1-14) under Subtask 4.4 and a sustained effort under Subtask 3.1 to capture additional textual information from TSCA regulatory letters.

Additionally, as the work assignment has progressed, the technical teams involved have identified additional analyses and support for specific projects. These include new work under Subtask 3 (Scientific Platform & Case Studies).

Finally, the time and expertise originally allotted for supporting Subtask 5 (Development and Prioritization of the EDSP Universe) has been reallocated to Subtask 3.

II. Background

This work assignment will provide technical support in three specific areas:

1. Support the development of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy under Section 4 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act via development of an inventory of testing requests and existing data and analysis of this inventory;
2. Support EDSP linear and pathway-based systematic literature reviews to support the performance-based validation of high throughput (HT) assays, computational models for the estrogen, androgen, and thyroid pathways and cross-species validation studies
3. Support collecting, prioritizing, and analyzing in vitro and in vivo data for display on the EPA Comptox dashboard via systematic review (SR) and high-throughput assays (in vitro only)

The Office of Science and Coordination Policy manages EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was established in 1998 under authorities contained in the 1996 Food Quality Protection Act (FQPA) and the 1996 Safe Drinking Water Act (SDWA) amendments. As mandated by these statutes, the EDSP develops a screening program to determine whether certain substances may have endocrine activity in humans and wildlife. The US EPA has developed a two tiered approach for screening chemicals and pesticides. The Tier 1 battery is used to identify substances that have potential to interact with the estrogen, androgen or thyroid hormone pathways. The Tier 2 tests identify and establish dose response information for adverse effects for substances identified in the Tier 1 screening. Beginning in 2015, the EDSP is incorporating ToxCast high throughput screening data and computational models in the prioritization and screening of a chemical's potential to interact with the endocrine system in humans and wildlife for a portion of the Tier 1 battery. This approach will allow nearly 20 times the current number of screenings to be performed while nearly eliminating animal testing, allowing the program to meet its goals with a relatively level budget.

The EPA's EDSP is continuing the development and validation of alternative testing methodologies (i.e., high throughput assays and computational tools) to prioritize and screen chemicals based on potential endocrine bioactivity and exposure--in particular, the estrogen, androgen, or thyroid hormone pathways in humans and wildlife. This increased use of alternative testing methodologies will improve the output of screening results allowing for greater coverage of the endocrine system.

I. Statement of Work

Subtask 1. Work Plan and Task Management

1. The contractor shall prepare and submit a work plan in accordance with the requirements of this contract. The work plan will describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles. Work under this subtask will include participating in conference calls, preparing monthly progress reports, and other task management activities.

2. Provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours Allocated	Hours used this month	Cumulative hours used

Through technical direction, the COR will identify topics to address, estimated hours for each topic, a deliverables due date, and background such as the names of EPA staff to contact for information.

3. Some work may require access to TSCA Confidential Business Information. The manager of this work assignment, as well as any staff working on reports that involve TSCA CBI, must be TSCA CBI cleared. They must also take supplementary CBI training designated by the EPA COR. Reports based on information drawn from TSCA CBI documents must be submitted to EPA as TSCA CBI, even if the contractor believes they have excluded CBI from the report. This is in addition to complying with all TSCA CBI requirements in the contract and in EPA's TSCA CBI Protection Manual.

4. The contractor shall immediately notify the EPA WA COR if there are any problems that affect the production and delivery of deliverables.

5. The contractor shall provide all deliverables in an electronic format specified by the EPA WA COR (e.g., Word, Excel, Access, HTML) via electronic mail. Unless otherwise specified by the EPA WA COR, Battelle shall provide a secure method for internet transfer of large files.

6. All Deliverables for WA 2-14 are the property of EPA (including any scripts or computer code developed accomplish analyses).

7. The contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

Subtask 2. Quality Assurance Project Plan (QAPP)

The contractor shall create a Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for subtasks 3, 4, and 5 in this SOW, as well as any specific quality assurance and quality control activities. The QAPP integrates all of the technical and quality aspects of the project in order to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. All work performed or funded by EPA that involves the acquisition of environmental data must have an approved QAPP. Details for developing a QAPP can be found at: https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf and the contractor shall be responsible for the development of, and any revisions to, the QAPP. Revisions to the QAPP must be made prior to beginning environmental data activities.

Subtask 3. Implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program

This Subtask fits specifically under the Contract SOW Task II. Data Analysis (II. 1 – 6).

1. **Data Processing on Testing Requests and Requirements**. The Contractor shall convert data from TSCA Section 4 & 5 regulatory letters and databases and TSCA Sections 4, 5, and 8 hazard and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links

for the chemical, guideline, case number, and associated text as pertains to each record. This amendment is for continuation of ongoing work under this subtask.

2. **Data Processing on Existing Chemical Data**. The Contractor shall convert data from TSCA Sections 4, 5, 6, and 8 hazard, exposure, and fate databases into a machine readable format (such as ASCII). The contractor shall establish database links for the chemical, guideline, case number, and associated text as pertains to each record. This amendment is for continuation of ongoing work under this subtask.
3. **Data Analysis.** The Contractor shall determine which tests are most commonly requested and determine trends of data requests based on chemical classes and other variables. This knowledge will be used to help optimize future testing strategy (data requests) and to determine tests that would most benefit from alternative testing strategies. This amendment is for continuation of ongoing work under this subtask.
    a. The Contractor shall support the curation, clustering, and prioritization of chemical substances from the TSCA Inventory including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.
4. **Scientific Platform.** The Contractor shall install and maintain software on the TSCA CBI LAN in support of this project and for the TSCA NAM Team to support the overall implementation of the TSCA Alternative Testing Strategy. This includes, but is not limited to, R environments and packages, Python environments and packages, relational and non-relational databases (MySQL, PostgreSQL, MongoDB, etc.).
5. **Case Studies.** The Contractor shall support the development and execution of TSCA Alternative Testing Strategy case studies including analysis of chemical structure, in vivo and in vitro data.

Subtask 4. EDSP linear and pathway-based systematic literature reviews

This Subtask contains elements under both Task II. Data Analysis (II. 4 - 6) and Task III. Technical Program Support - General Support (III.1, 2, & 4).

1. **Continuation of EDSP Linear Systematic Literature Reviews**. The Contractor shall continue to support EPA with scientific expertise to perform title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on the Fish Short-Term Reproduction Assay (FSTRA), and Male and Female Pubertal Assays initiated under EPW-11-063, Task Order 11; and the Amphibian Metamorphosis Assay and cross-species Fish Short Term Reproduction Assay initiated under EPW-11-063, Task Order 16. This amendment is for continuation of ongoing work under this subtask.
2. **EDSP pathway-based systematic literature reviews**. The Contractor shall assist EPA with developing and implementing approaches for pathway-based systematic literature reviews such as the steroidogenesis and thyroid-related pathways and molecular-initiating events (MIEs). Tasks include articles tagging, title/abstract screening, full-text screening, data extraction, and other annotations as directed by EPA on relevant articles, as well as template design, workflow management, and support of automated approaches. This amendment is for continuation of ongoing work under this subtask.
3. **Data management of EDSP Systematic Reviews.** The Contractor shall support the development and implementation EDSP and OECD Harmonized Templates, reviewer workflows, and reference management in systematic review tools selected by EPA. This amendment is for continuation of ongoing work under this subtask.
4. **Analysis of EDSP Systematic Reviews**. The Contractor shall support the data (including data cleaning), statistical (such as meta-analysis of studies), toxicological, and textual analysis (such as text mining and natural language processing analysis) of EDSP systematic reviews and other data streams. This amendment is for continuation of ongoing work, but includes a limitation on the number of hours (81) for the Steroidogenesis Meta-Analysis under this subtask.

~~Subtask 5: Development and Prioritization of the EDSP Universe 3.0~~

1. ~~The Contractor shall support the curation, clustering, and prioritization of chemical substances from the EDSP Universe of Chemicals including analysis of substance nomenclature, chemical structure, and data on physical-chemical properties, use and exposures, and toxicology.~~
2. ~~Develop an experimental data extraction and curation approach and/or QSAR model(s) to represent and associate relevant physical-chemical test data for each substance in the EDSP Universe 3.0~~
3. ~~Develop decision support framework and analysis to prioritize, deprioritize, exclude, and cluster substances for testing in EDSP relevant assays based on experimental or modelled physical-chemical properties or chemical structure.~~

II. Deliverables

The contractor shall provide deliverables as shown in Table 1.

Table 1. Deliverables and Schedule

Tasks	Deliverables	Due Dates
Subtask 1	Work plan and task management The contractor shall prepare and submit the work plan in accordance with contract requirements.	
Subtask 2	Quality Assurance Project Plan (QAPP) 1. Draft QAPP 2. Final QAPP	1. Draft: 10 days after WA begins 2. Prior to work on environmental data activities
Subtask 3	Implementation of the EPA Office of Pollution Prevention and Toxics (OPPT) Alternative Testing Strategy	At Work Assignment COR's request.
Subtask 4	EDSP linear and pathway-based systematic literature reviews	At Work Assignment COR's request.
Subtask 4.4	Steroidogenesis Meta-Analysis	As described in Steroidogenesis Deadlines and LOE table
~~Subtask 5~~	~~Development and Prioritization of the EDSP Universe~~	~~At Work Assignment COR's request.~~

1. EPA will approve the work plan within 30 days.
2. **A Quality Assurance Project Plan (QAPP) is required.** The contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a QAPP following OPPT/EPA guidelines. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained.
3. This work assignment involves the use of TSCA Confidential Business Information (CBI) for Task 2; otherwise, no CBI is involved.

4. Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

III. Period of Performance

This Work Assignment will start with the date of the Contracting Officer's signature and extend through June 12, 2019.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	Fish Tissue Data Migration

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-15. Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 06/13/2016 To 06/12/2019		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Samantha Fontenelle (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-2083 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

PERFORMANCE WORK STATEMENT
BATTELLE EP-W-16-017
Work Assignment 2-15

TITLE: Fish Tissue Data Migration

WORK ASSIGNMENT COR (WA-COR):

Samantha Fontenelle
Standards & Health Protection Division
US EPA (4305T)
Washington DC 20460
202-566-2083
202-566-0409 FAX

Lisa Larimer (Alternate)
202-566-1017
202-566-0409 FAX

PERIOD OF PERFORMANCE: Work Assignment issuance through 06/12/2019

I. Background and Scope of Work

Background

The National Listing of Fish Advisories (NLFA) is a national online database of fish advisories and fish tissue contaminant data collected by states, territories and tribes (hereafter states). It was developed in 1992 and includes advisory information for 50 states, District of Columbia, and the U.S. territories of American Samoa and Guam. It also includes fish tissue contaminant data which served as the basis for state-issued advisories for 48 states. Since 2000, the survey of fish advisories has been performed under an approved ICR for the National Listing of Advisories (OMB Control No. 2040-0226).

Scope of Work

Under this work assignment, the contractor shall assist EPA with the collection, standardization, and migration of state fish tissue contaminant data.

II. Tasks

Task 1 – Work Plan and Monthly Progress Report

The Contractor shall submit a work plan to the Agency within fifteen (15) calendar days of receipt of the WA. The contractor work plan shall describe tasks, approach, schedule, estimated direct labor hours by task and labor level, budget with costs broken down by line item; and proposed staff names, hours, and project roles.

The contractor shall provide a table in the Monthly Progress Report with the information shown below:

Memo # and date	Date due	EPA technical Contact	Contractor lead staff	Topic	Hours		
					Allocated	Used this month	Cum used

Task 2 – Quality Assurance Project Plan (QAPP)

A Quality Assurance Project Plan (QAPP) has been approved by the Contractor's quality assurance/quality control (QA/QC) officer and the EPA/OST QA/QC officers under WA 1-15. This document is a living document and updates shall be made as necessary (e.g., due to changes in scope, key personnel or approach). All deliverables shall include a report describing compliance with the QAPP. The work performed in this PWS shall conform to the Information Quality Guidelines (IQG) Checklist (Attachment A). The completed checklist and final QAPP shall be submitted with the final deliverables.

Task 3 - Data Management Plan

The Data Management Plan was revised under WA 1-15. The Contractor shall update this document as necessary to ensure that the approach for collecting, standardizing, and migrating state fish tissue data is appropriately documented for reproducibility.

Task 4 – Tissue Data Review, Standardization, and Collection

Data quality issues exist with the state fish tissue contaminant data in the NLFA. The Contractor shall assist EPA with the review of state tissue data and perform, as necessary, data cleanup to address data quality and other issues.

The contractor shall assist with standardizing chemical analyte name, species taxa, etc.; acquiring missing or additional data parameters (e.g., method detection limits, analytical methods, latitude/longitude, etc.); and addressing other data related issues. The data review and standardization shall be conducted to ensure that data migrated to STORET/WQX is of high quality and can be used for human health risk assessment purposes.

The Contractor shall work closely with EPA and each state to ensure that their data are correctly standardized and quality review for accuracy and completeness before they are migrated to STORET/WQX. For estimating purposes, the Contractor shall assume data from 8 states will be reviewed and standardized. The Contractor shall support EPA in obtaining missing or accurate fish tissue data from states, territories and tribes for timeframes specified by the WACOR. This task will require the Contractor work closely with states.

Task 5 – Data Collection and Migration

The Contractor shall add the standardized tissue data into the STORET/WQX and notify each state when its data have been migrated into STORET/WQX. For cost estimating purposes, the Contractor shall assume 50,000 fish tissue sample results shall be added to STORET/WQX.

Tasks 4 and 5 activities shall be conducted in concert for each state.

Task 6 General Technical Support

The contractor shall provide general technical support which may include responding to inquiries on state tissue data or on the NLFA database; preparing presentations and giving presentations. For estimating purposes, the Contractor may assume no more than two presentations will be prepared and given.

III. Deliverables

The Contractor shall prepare draft deliverable(s) for review by the EPA WACOR in accordance with the deliverable schedule in section IV or by technical direction (TD). In preparing final written deliverables the Contractor shall incorporate written comments from the EPA WACOR and submit the final deliverables in accordance with the deliverable schedule in section IV or TD. The EPA WACOR will review and approve all final deliverables.

Draft and final deliverables including reports, data, databases and maps shall be provided to the WACOR electronically. Electronic files shall be provided in PDF and/or in the original software (Excel, Word). The Contractor shall use Microsoft Office and Adobe Acrobat software for developing all electronic copies of deliverables associated with the work assignment.

IV. Schedule of Deliverables

Task	Deliverable	Schedule
1	Work Plan	Per contract requirements
2	Revised QAPP	As necessary and/or as requested by the WACOR
2	Final QAPP	One month before work assignment completion
2	Information Quality Guidelines	Within 10 business days of completion of the work assignment
3	Revised DMP	As necessary and/or as requested by the WACOR
3	Final DMP	One month before work assignment completion
4	Biweekly updates on status of standardization of state data	As requested by the WACOR
5	Status updates on data collection efforts	As requested by the WACOR

5	Status update on data migration	Within 5 business days of migration of state data
6	Draft presentations	As requested by the WACOR

IV. Reporting:

The Contractor shall include all progress for this WA in the monthly report prepared for this contract. The monthly report shall also include any QA issues encountered and recommendations for resolution. Financial reports shall also be completed as specified in the contract. Financial reports shall also be completed as specified in the contract. The Contractor shall maintain a file of all documentation, including raw data, calculations, assumptions, telephone contacts, and sources of information.

During the period of performance of this work, the contractor shall immediately inform the EPA WACOR by email of any problems that may impede performance along with any corrective actions needed to solve the problem.

V. Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

VI. Travel:

No travel is anticipated under this work assignment. However, any travel chargeable to this work assignment shall be allowable only in accordance with the limitation of FAR 31.205-43 and FAR 31.205-46, and must be approved by the EPA Project Officer prior to travel taking place.

VII. Printing:

All copying and printing shall be accomplished within the limitations of the printing clause of the contract.

VIII. Meetings, Conferences, Training Events, Award Ceremonies, and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, including the form 5170 for all meetings costing more than $20,000, shall be obtained by the EPA CL COR as needed and provided to the Contracting Officer Work under conference-related activities and expenses shall not occur until this approval is obtained and provided by the EPA CL COR.

ATTACHMENT A

Office of Water Information Quality Guidelines Checklist for Non-*Influential Information*

Office of Water
Information Quality Guidelines Checklist for
Non-Influential Information

☐ The information to be disseminated is covered under The Guidelines.

☐ The information is in compliance with EPA's Quality System and other related policies.

☐ The information is in compliance with Office of Water's Quality Management Plan.

☐ The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.

☐ Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.

☐ Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.

☐ Utility: the information is useful to the intended users.

☐ Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

_____ _____

Division Director's Signature & Date IQG Officer for OW Signature & Date

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-16

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-W-16-017	06/13/2016 To 06/12/2019 Base Option Period Number 2	TSCA Section 8a and CAIR

Contractor: BATTELLE MEMORIAL INSTITUTE

Specify Section and paragraph of Contract SOW:

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2018 To 06/12/2019

Comments:
Initiate work assignment for 2-16. Contractor shall provide work plan within 30 days of receipt of work assignment.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 06/13/2016 To 06/12/2019 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Tracey Klosterman (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-2209 FAX Number:
Project Officer Name: Tyrone Thomas (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-3121 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Keith Westry (Signature) (Date)	Branch/Mail Code: Phone Number: 202-564-9863 FAX Number:

STATEMENT OF WORK

Work Assignment (WA) Title: Technical Support for TSCA Section 8(a) PAIR/CAIR and Other TSCA Regulatory Activities

Contract Name: Battelle
Contract Number: EP-W-16-017
Work Assignment: #2-16

Contract Officer Representative (COR)
Tracey Klosterman, CITB, CCD, OPPT
Telephone: (202) 564-2209
E-mail: klosterman.tracey@epa.gov

Alternate Contract Officer Representative (COR) Technical Contact
Hannah Braun, CITB, CCD, OPPT
Telephone: (202) 564-5614
E-mail: braun.hannah@epa.gov

Mailing Address
U.S. EPA
1200 Pennsylvania Avenue, NW
Mail code: 7405M
Washington, DC 20460-0001

Courier Address
U.S. EPA
1201 Constitution Avenue, NW
Room 7405M, William Jefferson Clinton East Building
Washington, DC 20004

BACKGROUND

The collection of information under Section 8(a) PAIR and CAIR was regulated under the Toxic Substances Control Act (TSCA). The law, enacted in 1976, gives the Environmental Protection Agency (EPA) broad authority to identify and control substances that pose a threat to human health or the environment. Under TSCA Section 8(a), the Agency may require companies to maintain records and submit reports on their chemical manufacturing, importing, and processing activities. The agency has used its Section 8(a) authority to impose recordkeeping and reporting requirements on specific listed chemicals. In implementing its Section 8(a) authority, the Agency issued "model" rules that require submission of detailed production and exposure data on certain listed chemicals.

In an effort to make TSCA regulatory actions more readily available to other government agencies, as well as the public, CCD will utilize information contained in the CCD specific database to create an MS Access Database to populate the ChemView system for generation of ChemView Templates. All information uploaded into the ChemView system would not contain Confidential Business Information (CBI).

The purpose of this work assignment is to provide technical support to EPA for TSCA Section 8(a) PAIR/CAIR information under said rulemaking such as: (1) Prepare and develop a template consistent

with the current ChemView format to represent the information captured in TSCA Section (a) CAIR/PAIR collection (2) collection, review, and formatting of supporting and documents, (3) coordination of chemical identity verification, (4) data entry of information into the approved CCD/ChemView database, and (5) provide technical assistance to EPA COR s in uploading the resulting MS Access Database files into ChemView. This work assignment will not involve the use of TSCA Confidential Business Information.

Additionally, the work assignment will provide support in document retrieval, collection, indexing and digitization for other TSCA regulating authorities and support completion of requests for information. This portion of the assignment, which may include collections of documents or materials for external requests, will be handled upon request via the COR in writing.

The contractor will be required to have CBI clearance for this portion of the research and collection of materials, as some materials may be Confidential Business Information (CBI) and thus, should be handled accordingly.

PERIOD OF PERFORMANCE: Date of approval through June 12, 2019.

LEVEL OF EFFORT (LOE): The estimated LOE for this Work Assignment is 1,000 hours.

Task 1: Quality Assurance Project Plan

This task will involve the preparation of a Quality Assurance Project Plan (QAPP). Under this task the Contractor shall prepare a QAPP to describe the quality assurance practices the Contractor will use to perform the work described in the tasks below.

Task 2: Collection of Supporting Documents

The contactor shall initiate collection of supporting and source documents including Federal Register Notices and TSCA Section 8(a) PAIR/CAIR documents as identified by the COR in written technical direction. The Contractor shall utilize all available resources, including the Documentum and CIS databases, individual network directories, hard copy files, etc., for collection of the documents. The documents collected in this manner do not contain CBI. In some instances, when the documents are not located in an Agency environment, they may be located on public websites including, but not limited to Regulations.gov, Pubchem, and HeinOnline.

The contractor shall create a pdf copy of all identified documents for which pdf files are not already available. If the documents are not available electronically, the Contractor shall create a scanned image of the document and convert it to a text searchable pdf format. The EPA Contract Officer Representative (COR) shall provide guidance on naming and storage of the collected documents. The Contractor shall notify the Contract Officer Representative (COR) of any files which are missing.

Task 3: Formatting of Supporting Documents

The contractor shall provide technical assistance to the COR in formatting of supporting documents as Adobe pdfs. The COR shall provide written guidance on the formatting requirements, including suitable metadata requirements for publication in the ChemView system. Formatted pdf documents must be text searchable to accommodate the functionality within the ChemView system. The COR shall provide written guidance on collection of other TSCA regulatory actions or records whereby the Agency is requesting supporting in research, collection and digital management of said records.

The contractor shall track the progress of completion of these formatted documents and verify that completed reports have been posted to the correct location. For all assigned tasks, the contractor shall notify the COR of any delays in completion of the reports, and to obtain any items that are not available. As the EPA contact, the COR is responsible for certifying that all formatted documents are suitable for transmission to the ChemView system, for public dissemination, or for receipt by other EPA staff for review and eventual public dissemination.

Task 4: Template Development for TSCA Section 8(a) PAIR/CAIR Information

The contractor shall provide technical assistance to the COR in the development and formatting of the template that will be used to consistently format the TSCA Section 8(a) CAIR/PAIR information. The COR shall provide written guidance and examples of templates of TSCA sections/program information that have been incorporated into ChemView thus far as examples for template development of the TSCA Section 8 (a) information. The contractor shall generator and draft a template accordingly, working with the Technical Contact for guidance. Lastly, they will use samples of extracted data to complete a template draft in order to ensure the template is complete, consistent, and contains all necessary information that pertains to the TSCA Section 8(a) information.

Task 5: TSCA Section 8(a) PAIR/CAIR database

The contractor shall use the collected TSCA Section 8(a) PAIR/CAIR Notices and materials for review and population to the tables within the CCD approved database. All identified chemicals shall be entered into the system using guidance as provided by the COR. Process will include the completion of a data worksheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the COR. Using the information contained in the database, the contractor shall create MS Access database files for upload into the ChemView system. The ChemView workgroup will review all data and uploaded support documents prior to final approval and publication in the public ChemView database.

5.1 Chemical Identity Verification

The contractor shall review and capture information from the non-CBI documents to populate the chemical identities included in the TSCA Section 8(a) PAIR or CAIR documentation. This identity will include the Non-Confidential Name, as well as any public CAS/Accession Number where available. The COR shall provide written guidance on what sources and naming conventions shall be used. Due to the vast number of intended users of the system, the chemical identity requirements may vary depending on the intended report. In instances where multiple names are available for a given chemical, the contractor shall provide what information is available, and the EPA COR will coordinate verification of the suitable names.

5.2 Database Data Entry

The contractor shall use the non-confidential documents collected, and guidance provided by the COR to enter data into the CCD approved database. The written guidance shall detail the specific fields, formatting requirements, and examples of where the information can be found for each data field. The contractor shall pose any questions to the COR as soon as possible to allow additional guidance to be provided.

In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the COR to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the COR.

5.3 Report Generation

The contractor shall assist the EPA COR in creation of various reports using the export functions of the CCD approved database. The contractor shall coordinate with the COR the procedures for generation of the reports and any formatting requirements that may be needed.

Task 6: Research and Collection of TSCA Regulatory Activities and Information

The contractor shall provide support to EPA staff in the documents and materials retrieval, collection, indexing and digitization for other TSCA regulating authorities and support completion of requests for information. All requests for support and research collection will be made directly to the COR. The contractor will be provided with a reasonable timeline for completion of collection of materials.
All identified material shall be entered into an index log system on an MS Access system, maintained by the contractor, but kept by the Agency/ COR. In addition, the database contains a "Comment" field designed for the contractor to enter any comments, observations, or notes they wish the COR to review. This will allow for a formal accounting of what information was exchanged and allow for future improvements to guidance documents and/or enhancements to the database. All edits to the database shall be at the direction of the COR.

The contractor should use all available sources for the collection of the documents including the Documentum and CIS databases (e.g., electronic version of the files from the Confidential Business Information Center--CBIC, PMN Gold Workflow System, the CBI Local Area Network (LAN), individual network directories, hard copy files, etc.). The contractor will go to each of the known sources to find documents relating to each inquiry or substance case request to identify the correct document. Documents corresponding to related requests, chemical inquiries, etc. will be utilized for information gathering purposes for the purposes of this work assignment. Should the documents collected contain CBI information, the contractor will begin the initial sanitization of the documents and provide them to the COR after completion of the sanitization process. The contractor shall provide support to completely and accurately remove CBI from documents. The COR and/or EPA staff will review for CBI content before returning to contractor or revision or completion of sanitization activity.

When the documents are not located in a CBI environment, they may be located on public websites such as Regulations.gov, Pubchem, and HeinOnline. Subscription or licensing fees may apply to obtain copyright documents that are not in the public domain.

Said task further includes making copies of documents and/or digitizing the paper collection. Process will include the completion of a data log sheet, entry of the required data into the appropriate data tables, and QA/QC of the information for quality assurance purposes according to the approved QAPP. Any identified missing or questionable content shall be reported to the COR.

The COR and supporting CCD staff will review all data and content of supporting documents prior to final approval and release for public dissemination, including use by other Federal or non-Federal entities. The task is completed on as needed support role by the Contractor via the COR.

Section A SPECIAL TRAINING REQUIREMENTS/CERTIFICATION

All staff supporting this Work Assignment will possess all necessary education requirements and credentials before performing work. All project personnel will have a working knowledge of TSCA. Any staff not specifically listed above will be fully trained prior to performing any work on this project.

All contract staff handling CBI under this Work Assignment are certified to do so under the contractor's and EPA's existing, approved TSCA CBI Security Plan. This Security Plan specifies that before contractor staff members are permitted to have access to CBI, they are required to have completed CBI Security Training. Once staff members have successfully tested on the information covered in this training, they receive CBI Security certification and are placed on the contract's Access Control List of the contracting staff authorized to access CBI under this Work Assignment. Staff on this list renew their training certification annually.

DELIVERABLES: All deliverables shall be submitted to the COR electronically (Adobe pdf).

Task 1 The Contractor shall submit a QAPP within 2 weeks of approval of the work plan.

Task 2 The contractor shall submit to the EPA COR written updates on the status of completion of the tasks on a monthly basis. The update should include identification of any missing documents.

Task 3 The contractor shall submit to the COR written updates on the completion of the subtasks in this task on a monthly basis. The update should include reporting of progress of documents formatted, notification of any quality issues or concerns for these documents, and reporting of documents ready for COR review.

Task 4 The contractor shall submit to the COR written updates on completion of the subtasks in this task on a monthly basis. The update should include reporting on the progress of template development, chemical identity verification, including notation of changes in identities and any updates made to the CCD approved database. The contractor shall report progress on the completion of the data entry.

ADDITIONAL INFORMATION

- Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent views of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.
- In an effort to maintain standards during review and completion of all tasks, an audit of data quality may be performed upon request to assess the accuracy and completeness of factual data processing, data entry, or CBI sanitization to ensure submitted work products are of high quality and meet the quality standards for this Work Assignment